UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE GENZYME CORP. SECURITIES LITIGATION	Case No. 1:09-cv-11267-GAO

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT GENZYME CORPORATION'S MOTION TO DISMISS CONSOLIDATED CLASS ACTION COMPLAINT

John D. Donovan, Jr. (BBO# 130950)
Robert G. Jones (BBO# 630767)
Alison E.H. McLaughlin (BBO# 663060)
ROPES & GRAY LLP
One International Place
Boston, Massachusetts 02110
(617) 951-7000 (Tel)
(617) 951-7050 (Fax)
john.donovan@ropesgray.com
robert.jones@ropesgray.com
alison.mclaughlin@ropesgray.com

Counsel for Defendant Genzyme Corporation

June 2, 2010

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

CASES

STATUTES

OTHER AUTHORITIES

PRELIMINARY STATEMENT

In September 2008, a rare virus — "Vesivirus 2117" — contaminated a bioreactor engaged in a pre-manufacturing "process validation" run at Genzyme Corporation's ("Genzyme") new facility in Geel, Belgium. The same unusual virus subsequently contaminated two bioreactors at Genzyme's Allston, Massachusetts manufacturing facility. In the wake of these events, in June of 2009, Genzyme suspended production in Allston of two key products — Cerezyme and Fabrazyme — in order to sanitize the facility. Inventories of those products were not sufficient to meet patient demand, and the shortages adversely affected Genzyme's revenues. The Company's stock price fell.

Separately, the Food and Drug Administration ("FDA") has over the years conducted multiple inspections of Genzyme's Allston Facility. The FDA made "observations" to Genzyme about certain production issues in 2008, escalated its commentary into a "warning" in 2009, issued additional "observations" in late 2009, and ultimately executed a consent decree with Genzyme in 2010. These regulatory matters had no effect on actual bulk production of Genzyme products in bioreactors, instead primarily relating to certain "fill and finish" operations at the Allston plant. But the FDA conditioned its approval of a new product to be manufactured at Allston — called Lumizyme — on Genzyme's satisfactory resolution of the "fill-finish" issues the FDA had raised. At the same time, Genzyme continued to produce the product for commercial sale as it always had in smaller scale facilities, under the name Myozyme.

Both of these circumstances unquestionably presented challenges to Genzyme. But the plaintiffs seize upon these separate events, and mash them together to claim that Genzyme was engaged in "rampant" violations of current Good Manufacturing Practices ("cGMPs"), and suffered from "woefully deficient" compliance policies, making "contamination outbreaks," "adulteration of its products" and "serious adverse FDA action" "likely if not inevitable." And

they claim that virtually every statement Genzyme made for two years — even just announcing quarterly results — was "false and misleading" because the Company did not simultaneously confess to the plaintiffs' charge, disclose every communication back-and-forth with the FDA, or predict both regulatory action and unprecedented contamination events. The plaintiffs press the conclusion that because adverse events unfolded, Genzyme purposefully knew, but concealed, that they would actually eventuate. According to the plaintiffs, Genzyme "intentionally" omitted to predict "inevitable" regulatory action and both the fact and consequences of contamination in order to deceive investors and pump up the stock price.

But that charge depends on the coupling of regulatory "fill-finish" observations with the extraordinary event of viral contamination, and exaggerating the result into an allegation of "rampant" breaches of manufacturing standards. The Complaint then takes that essential claim about ostensible "mismanagement" of manufacturing processes and impermissibly wraps it in "disclosure" clothing, all the while ignoring what Genzyme *actually* said publicly throughout the ostensible class period, in order to shoehorn a factually implausible theory into the federal securities laws. And finally, the plaintiffs simply presume a guilty conscience. Without attributing any conceivable motive to deceive to any Genzyme officer, they charge that because the Company "knew" what the plaintiffs claim, it deliberately kept investors in the dark.

Plaintiffs' claim is accordingly nothing more than opportunism masquerading as securities "fraud." The federal securities laws require more. *Any* complaint must include "enough to raise a right to relief above the speculative level," *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007), such that the complaint establishes "'a plausible entitlement to relief,'" *Vernet v. Serrano-Torres*, 566 F.3d 254, 258 (1st Cir. 2009) (quoting *Twombly*, 550 U.S. at 559). But a securities complaint must also "specify each statement alleged to have been misleading

[and] the reason or reasons why the statement is misleading," 15 U.S.C. § 78u-4(b)(1) (2010), and "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind," 15 U.S.C. § 78u-4(b)(2) (2010), such that the inference of intentional or reckless deception is "cogent and at least as compelling as any opposing inference one could draw from the facts alleged," *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 324 (2007). Those requirements are not met here. The extensive two-year fraud posited in the Complaint is all speculation and no plausibility.

At bottom, the plaintiffs lift a series of facts disclosed to investors during (or even after) the class period and allege that the information should have been disclosed earlier. For example, although Genzyme announced in Spring 2009 that two bioreactor failures in late 2008 were caused by viral contamination, the plaintiffs allege that Genzyme had a duty to disclose the fact of a viral contamination *sooner*. But the pleading does not say what information Genzyme possessed any earlier that would have even allowed it to make a disclosure; and they simply ignore Genzyme's statement that it took six months of investigation to isolate the viral cause. Similarly, although Genzyme announced in November 2008 that the FDA extended the date by which the agency expected to approve a large-scale production process application, the plaintiffs simply allege the disclosure should have been made earlier. But when? And what did Genzyme know that would have allowed it to predict the regulator's delay? The entire structure of the Complaint follows this same pattern: disclosures the Company *did* make during the class period are used to allege — *without more* — that Genzyme had a duty to disclose the information at an earlier time.

Quite apart from its failure to supply the building blocks of information that would permit "earlier" disclosure, the pleading provides no basis upon which to draw an inference that the

failure to do so was intentionally or recklessly deceptive. Again, what Genzyme *did* disclose corroborates the point: It strains credulity to assert that Genzyme would *conceal* from the public information that the Company actually *disclosed.* For example, Genzyme:[1]

- Announced to the public each time the FDA moved an anticipated approval date for its products, including Lumizyme.
- Announced to the public when it received a Warning Letter discussing the FDA's observations concerning certain aspects of the Company's operations in Allston, Massachusetts.
- Announced to the public immediately upon deciding to shut down the Allston plant for decontamination activities following the identification of a viral contamination of a bioreactor producing the product Cerezyme in late May 2009.
- Informed its regulators and the public when supplies of Myozyme and other products became tight or unavailable.

The steady stream of disclosures and updates by Genzyme during the period — either omitted from the pleadings or downplayed by the plaintiffs for obvious reasons — overwhelms the inference of purposeful deception the plaintiffs simply manufacture. And there is nothing else. The complaint offers no reason behind its charge of "concealment." It doesn't hint at a motive or begin to say "why" Genzyme would risk failing to alert investors to material risks. The pleading simply chalks up its claim of omitted disclosure to "fraud" without a basis, much less particularized facts.

The Complaint also mocks the requirement set by Fed. R. Civ. P. 9(b) and the PSLRA that each purportedly misleading statement be specified, along with the alleged reason why the statement is misleading. *See Aldridge v. A.T. Cross Corp.*, 284 F.3d 72, 78 (1st Cir. 2002).

[1] The general rule that documents outside of the pleadings are not considered on a motion to dismiss does not apply to certain categories of documents including, *inter alia*, "documents central to the plaintiff's claim" and "documents sufficiently referred to in the complaint." *In re Praecis Pharms., Inc., Sec. Litig.*, No. 04-CV-12581, 2007 WL 951695, at *5 n. 8 (D. Mass. Mar. 28, 2007) (granting motion to dismiss Section 10(b) claim and citing *Watterson v. Page*, 987 F.2d 1, 3 (1st Cir. 1993)). Because the voluminous Complaint references and relies upon, specifically or generally, a large number of documents ranging from FDA correspondence to Genzyme's public disclosures, the defendants have addressed these documents as necessary herein and have attached copies for the Court's convenience to the Declaration of Alison McLaughlin ("McL. Decl."), filed concurrently herewith.

While the Complaint's length is striking, the puzzle-like structure of its section purporting to identify the alleged misleading statements and omissions, ¶¶ 216 to 320, is its most defining feature. Across 104 paragraphs, the plaintiffs purport to identify the countless statements they claim were "false or misleading." But the format of the pleading makes a game out of the task of identifying which statements are alleged to be false, and precisely how they are alleged to be false. Several statements are identified in a series, *see, e.g.*, Compl. ¶¶ 216-219 or ¶¶ 237-240, without any specific reason why each statement is purportedly false or misleading, and only then is that *group* of statements — which may not be related to one another at all — followed by a paragraph stating that all of the statements in previous paragraphs were false and misleading for any one of several reasons offered as a group. *See, e.g.*, Compl. ¶ 220 or ¶ 241. It is left to the Court and the defendants to guess at which reason aligns with any statement.[2]

This chaotic approach to pleading itself justifies dismissal. *See In re Alcatel Sec. Litig.*, 382 F. Supp. 2d 513, 534 (S.D.N.Y. 2005). Given the time plaintiffs had to prepare the Complaint, its confusing structure can only have been a tactical choice intended to give the appearance of a broad scheme to defraud where a genuine basis for the claim is lacking. But whatever the goal, the approach taken by the plaintiffs massively complicates the Court's task of evaluating the allegations on a statement-by-statement basis. *See In re Credit Suisse First Boston Corp.*, 431 F.3d 36, 49 (1st Cir. 2005).

Nonetheless, the allegations are susceptible of some attempt at organization. Close examination of the Complaint reveals that almost 50% of the alleged misstatements specified address Genzyme's expectations for the timing of the FDA's decision on approval of Lumizyme, which was the name given to Myozyme in 2000L formulation. The remaining statements also

[2] To assist the Court in solving the puzzle, the defendants have collected all of the purported misstatements in single chart, associating each statement with the list of conclusory reasons which allegedly render each statement misleading. This chart is provided as Attachment 1 hereto.

can be grouped into distinct categories, such as (i) general statements of optimism, or puffery; (ii) revenue guidance and financial results; and (iii) non-actionable forward-looking statements. For the purposes of establishing the legal insufficiency of the Complaint for purposes of Rule 12(b)(6), the defendants have organized their arguments around these and other categories.

Once organized, the claims are susceptible to straightforward legal analysis. For example, the central thrust of the Complaint is the plaintiffs' insistence that Genzyme was required to disclose "observations" made by FDA in connection with its inspection of the Company's Allston plant in October 2008 (and provided to Genzyme in writing on FDA Form 483). Indeed, *all* of the manufacturing conditions cited by the plaintiffs and alleged to have been omitted from disclosures to investors are lifted from observations contained in the Form 483 received by Genzyme in October 2008. But the cases clearly state that Form 483 observations by the FDA are not material and do not require disclosure. *See* Section II. A., *infra*. The plaintiffs also point to the Form 483 observations and claim that Genzyme was required to disclose that it was in "violation of cGMPs." But the cases also clearly state that such violations are established only at the time of an FDA enforcement action — not by the receipt of a Form 483 alone. *See* Sections II. A, B., *infra*. The plaintiffs cite nearly all of Genzyme's earnings and revenue guidance statements during the two-year period. But the Complaint nowhere explains how such reports were wrong, or whether the supposedly "correct" numbers would have been materially different — allegations which are required in order for claims challenging reported results or guidance to be actionable. *See* Section III. E., *infra*. The vast bulk of the alleged misstatements are non-actionable puffery or forward-looking statements. *See* Sections III. D. and III. E., *infra*. Taken together, the assorted claims and alleged misstatements and omissions simply are not actionable under Section 10(b) of the Exchange Act (or Rule 10b-5 there under).

This case underscores the wisdom of the heightened standards imposed on securities fraud claims by both Congress and the courts. Genzyme has faced countless challenges over the past two years. In doing so, it has worked with regulators, stakeholders, patients and investors to provide timely and appropriate disclosures to the public as events warranted. Even today, that work continues.[3] But companies are not subject to liability under the federal securities laws merely because they experience operational set-backs and declines in their stock price; after-the-fact assertions of "poor management" do not give rise to actionable claims under Section 10(b). *Santa Fe Indus. v. Green*, 430 U.S. 462, 479 (1977). If public companies facing such challenges can be routinely subject to expensive and time-consuming litigation and discovery on the basis of claims which merely speculate concerning its motives and insinuate that disclosures were incomplete or untimely, the Supreme Court's decisions in *Twombly* and *Tellabs*, and other standards applicable to such claims, have little practical effect. To be sure, the Complaint is lengthy and artful, but it lacks any legal merit. It fails to state a plausible claim upon which relief may be granted. This Court should dismiss it with prejudice.

FACTUAL BACKGROUND

Genzyme is one of the world's leading biotechnology companies. Genzyme focuses on the development of products to treat patients suffering from rare inherited disorders and other serious conditions. The company's Genetic Disease Segment has developed and manufactures products that treat lysosomal storage diseases — a group of metabolic disorders caused by a body's lack of certain enzymes — including Cerezyme® (for the treatment of Gaucher disease),

[3] While the Court need not consider these facts on this motion, on May 24, 2010, Genzyme announced that it had finalized the terms of a consent decree with the FDA (and agreed to a civil fine) in an effort to address manufacturing concerns raised by the agency, and on May 25, 2010, Genzyme announced that it had obtained FDA regulatory approval for the sale of Lumizyme manufactured at the 4000L scale to patients in the United States.

Fabrazyme® (for the treatment of Fabry disease), and Myozyme® (for the treatment of Pompe disease). Compl. ¶¶ 36-39.

These products are classified as "biologics" because they are created from biological rather than chemical sources. Compl. ¶ 35. Their manufacture involves the use of bioreactors in which the material that will be incorporated into the finished pharmaceutical product is "grown" before moving through the rest of the manufacturing process. *Id*. Genzyme operates a number of facilities worldwide that play some role in its biologics manufacturing, including at Allston Landing, Massachusetts (the "Allston Facility") and Geel, Belgium (the "Geel Facility").

***Myozyme and Lumizyme*.** Genzyme has produced Myozyme since 2006 at two of its facilities: one in Framingham, Massachusetts in 160-liter ("160L") bioreactors, which had been approved for patients in the United States, and another at its Allston Facility in 2000-liter ("2000L") bioreactors, which had been approved for use only outside the United States. Compl. ¶¶ 14, 48. Demand for Myozyme motivated the Company to pursue the use of larger bioreactors to increase production volume. Genzyme accordingly began to pursue production of Myozyme at the 4000L scale at the Geel Facility and FDA approval of 2000L Myozyme produced at the Allston Facility. Compl. ¶¶ 48-51. Because the Geel Facility was a completely new manufacturing site, the process for beginning and obtaining regulatory approval for production of Myozyme at the 4000L scale required completion of a lengthy "start up" phase. Genzyme began this process in mid-2008 and obtained approval of the European Medicines Agency ("EMEA") to produce and sell Myozyme at the 4000L scale on February 26, 2009 — months earlier than the Company had originally projected. Compl. ¶ 51.

Genzyme also undertook to secure approval from the FDA to sell Myozyme made at Allston at the 2000L scale. *See* Compl. ¶ 48. After the FDA determined that Myozyme

produced at this 2000L scale should be addressed under a separate Biologics License Application ("BLA"), rather than merely an amendment to its prior approval decision for Myozyme produced at the 160L scale, Genzyme gave the 2000L scale product a separate name — Lumizyme — for purposes of differentiation. Compl. ¶¶ 48, 49. In connection with the Lumizyme BLA, the FDA provided Genzyme with a PDUFA[4] date of November 29, 2008, and began its own inspection process for the BLA, including a review of the manufacturing processes at the Allston Facility that were to be involved in producing Lumizyme. Compl. ¶ 93.

The October 2008 Form 483. Between mid-September and mid-October 2008, just a few months after the EMEA certified that the Allston Facility was in compliance with cGMPs, the FDA conducted an inspection of the Allston Facility. On October 10, 2008, the FDA issued a Form 483 to Genzyme, identifying certain "observations" from the inspection process relating to Genzyme's manufacturing operations (the "Form 483"). *See* McL. Decl. Ex. A. The Form 483 contains standard language advising as follows:

> THIS DOCUMENT LISTS . . . INSPECTIONAL OBSERVATIONS AND DO[ES] NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE.

See id. (capitalization in original). The bulk of the FDA's observations were related to the "fill and finish" manufacturing processes that are "downstream" of the bioreactors where Genzyme later experienced two viral contamination events. *See id.* Nothing in the Form 483 addressed deficiencies at Allston in detecting or preventing viral contaminations. *See id*.

Upon receipt of the FDA's observations in the Form 483, Genzyme began to address the observations and communicated regularly — and publicly — with the FDA. *See* Compl. ¶¶ 101,

[4] PDUFA refers to the Prescription Drug User Fee Act of 1992, which requires the FDA to set goals for the amount of time it will take to review an application. Compl. ¶ 93. Thus, a "PDUFA date" is the date by which the FDA has informed the applicant that the agency will endeavor to reach a decision on the BLA.

278. Genzyme sent the FDA a voluntary written response to the Form 483 on October 31, 2008, detailing the Company's efforts to address each of the inspection observations and its progress in resolving them. *See* McL. Decl. Ex. B; Compl. ¶ 100.

Extension of Lumizyme PDUFA Date. In late October 2008, Genzyme appeared before an FDA Advisory Committee to discuss the results from Lumizyme clinical studies. In an important step towards obtaining FDA approval, the Advisory Committee voted 16-1 in support of the conclusion that Genzyme's studies established the clinical effectiveness of the therapy. McL. Decl. Ex. C. In November, Genzyme submitted, at the FDA's request, its Risk Evaluation and Mitigation Strategy ("REMS"). McL. Decl. Ex. D. On November 17, 2008, Genzyme issued a press release announcing that the FDA had extended the Lumizyme BLA PDUFA date by 90 days, to February 28, 2009. *See id.*; Compl. ¶ 106. The FDA had informed Genzyme that the extension was necessary to allow the FDA to review the REMS and to give Genzyme time to design a post-approval clinical verification study. *See* McL. Decl. Ex. D. Genzyme also informed investors that the Company did not expect the PDUFA extension to affect its previously issued earnings guidance. *See id.*

The February 2009 Warning Letter And Complete Response Letter. The FDA issued a warning letter (the "Warning Letter") regarding the Allston Facility on February 27, 2009, citing some of the same observations identified in the Form 483. *See* McL. Decl. Ex. E; Compl. ¶¶ 112-13. Again, the Warning Letter did not make any reference to the detection or prevention of viral contamination. *See* McL. Decl. Exs. A, E.

Also, on February 27, 2009, the FDA sent Genzyme a Complete Response Letter, indicating that approval of the Lumizyme BLA would be withheld until discussions regarding REMS and the post-approval clinical verification study, the two issues that had given rise to the

PDUFA date extension in November 2008 (see above) were resolved, and until the Company resolved the issues raised in the Warning Letter. *See* McL. Decl. Ex. F. Genzyme promptly disclosed these letters on the first business day after receipt. *See* Compl. ¶¶ 274-75.

Continuing Efforts Re: Lumizyme Approval. Following its receipt of the Warning Letter and the Complete Response Letter, Genzyme remained in regular communication with the FDA regarding the Company's progress, as it repeatedly disclosed to investors. *See, e.g.*, Compl. ¶¶ 278, 294, 297. The FDA conducted additional inspections of the Allston Facility in May 2009 and again in October to November 2009, issuing additional inspection observations on November 13, 2009. *See* Compl. ¶¶ 163, 183.

2008 Geel And Allston Bioreactor Run Failures. In 2008, the Geel Facility was in the "start up" phase of producing Myozyme at the 4000L scale. At that time, Myozyme produced at the Geel Facility was not approved for sale in any market. *See* Compl. ¶ 51. Bioreactors at that site were in the "process validation" stage, during which bioreactor process validation runs ("PV runs") are completed to confirm reliability and consistency of operation. In late September 2008, one of the PV runs experienced an unexpected decline in cell productivity. *See* Compl. ¶ 95. Rapid cell death during bioreactor runs is not uncommon in the manufacture of biologics, and may be caused by bacteria, equipment failure, viruses or other causes. Genzyme immediately initiated an investigation to determine the cause of the event. While that investigation was ongoing, the Geel Facility resumed PV runs and successfully completed the process validation stage of the regulatory approval process. After September 2008, no other incident of rapid cell death was observed at the Geel Facility and Genzyme received EMEA approval for 4000L Myozyme in late February 2009. Compl. ¶¶ 51, 111. This approval came several months *earlier*

than Genzyme expected, having advised the market earlier that month that such approval was anticipated for April 2009. *See* McL. Decl. Ex. G.

In November 2008, Genzyme observed a decline in cell productivity in a bioreactor in Allston used in the production of Myozyme at the 2000L scale for commercial sale in Europe, where it had already been approved. Compl. ¶¶ 96, 256. Genzyme promptly initiated an investigation, decontaminated the suite that houses the bioreactor, and quickly returned it to service. Even in the months prior to the November 2008 event, Genzyme had cautioned the market that Myozyme supplies would be constrained during early 2009.[5] On January 13, 2009, the Company announced that it had been working with a Myozyme stakeholder group (including physicians and patient groups) on a Supply Management Plan to assist in managing the availability of the therapy to patients during a period of tight supply. McL. Decl. Ex. J. On January 16, 2009, the EMEA issued a press release addressing the Myozyme supply shortage and Genzyme's Supply Management Plan, specifically noting that "problems with the manufacture of the medicine at some sites" as well as demand outpacing supply had contributed to the shortages. McL. Decl. Ex. K. The EMEA press release also noted that Genzyme was investigating the cause of the production problems at the sites. *Id.* Genzyme conducted its investigation into the cause of these two events over a period of six months, and on June 16, 2009, announced it had determined that both the Geel and Allston events had been caused by a rare virus.[6]

[5] *See, e.g.*, Compl. ¶¶ 238 (Tr. of Earnings Conf. Call, July 23, 2008), 258 (Form 10-Q for 3Q 2008, Oct. 22, 2008); McL. Decl. Ex. H (Press Release and Form 8-K, Feb. 13, 2008) ("This [first quarter EPS] estimate also reflects the U.S. introduction of Myozyme® (alglucosidase alfa), which has been constrained by limited product supply, as the FDA has yet to approve the larger scale manufacturing process for this product. This supply constraint will have an estimated impact of $0.03 per diluted share during the first quarter."); McL. Decl. Ex. I at 41 (Form 10-Q for 2Q 2008, Aug. 11, 2008) ("Product supply of Myozyme in 2009 is expected to be particularly tight until production at the 4000L scale at this facility is approved.").

[6] *See* McL. Decl. Ex. L (Press Release, June 16, 2009) ("Genzyme has now confirmed that this virus was the cause of declines in cell productivity at its Allston and Geel facilities in two previous instances in 2008, which were

***2009 Allston Bioreactor Run Failure*.** In late May 2009, Genzyme also experienced a decline in cell productivity in a second Allston bioreactor, this one manufacturing Cerezyme. Compl. ¶ 139. Based on the results of the investigation it was then completing for the 2008 Geel and Allston events, the Company was able to confirm quickly that the cause had been a virus, and on June 16, 2009, immediately disclosed the occurrence of the three events and the Company's conclusion that all three were attributable to a rare virus, Vesivirus 2117. *See* Compl. ¶¶ 139, 304. Genzyme also promptly took the precautionary action of shutting down the Allston Facility for six-to-eight weeks and decontaminating the plant. Compl. ¶ 140. Genzyme also disclosed that, unlike the first two bioreactor events, the shut down of the entire Allston Facility for decontamination would have a material impact on the Company's earnings. *See* Compl. ¶¶ 140, 304.

***FDA's Fall 2009 Re-inspection at Allston*.** In July 2009, the FDA informed Genzyme that it would re-inspect the Allston Facility in the Fall. McL. Decl. Ex. N; Compl. ¶¶ 162, 163. Following that re-inspection, on November 13, the last day of the class period, the FDA issued Genzyme a second Form 483, McL. Decl. Ex. O, as well as a Complete Response Letter, which again withheld Lumizyme approval, McL. Decl. Ex. P. Genzyme disclosed receipt of the Form 483 and Complete Response Letter the next business day. McL. Decl. Ex. Q (Press Release, Nov. 16, 2009). Also on November 13, Genzyme issued a press release disclosing the presence of foreign particles in a small number of vials of drugs manufactured at the Allston Facility. McL. Decl. Ex. R.

---

subsequently fully addressed."); Ex. M (Tr. of Analysts' Conf. Call, June 24, 2009) ("[I]t was only as a result of a six month long investigation that we were able to create the specific PCR [test], which allows us to isolate and identify this virus.").

ARGUMENT

Plaintiffs looking to establish liability for violations of Section 10(b) of the Exchange Act and Rule 10b-5 must satisfy the following elements: (1) a false statement or omission of a material fact; (2) made with scienter; (3) in connection with the purchase or sale of a security; (4) upon which the plaintiff reasonably relied; (5) an economic loss; and (6) that the loss was caused by the misrepresentation or omission. *In re Boston Scientific Corp. Sec. Litig.*, 490 F. Supp. 2d 142, 153 (D. Mass. 2007) (citing *Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 341 (2005)). Moreover, the PSLRA and controlling decisions of the Supreme Court and First Circuit impose "heightened" pleading standards on securities plaintiffs. To avoid dismissal under Fed. R. Civ. P. 12(b)(6) and 9(b), a plaintiff must allege "with particularity" the circumstances amounting to fraud, including particularized facts supporting a "cogent and compelling" inference that the defendants intentionally or recklessly acted to deceive investors. The fundamental pleading principle that factual allegations must be "enough to raise a right to relief above the speculative level," *Twombly*, 550 U.S. at 555, such that the complaint establishes "'a plausible entitlement to relief,'" *Vernet*, 566 F.3d at 258 (quoting *Twombly*, 550 U.S. at 559), are elevated in the securities context. The "who, what, where, and when" of a claim of misrepresentations or omissions must be accompanied by "why" the circumstances can be chalked up to *fraud*.

I. THE COMPLAINT SHOULD BE DISMISSED BECAUSE IT FAILS TO SATISFY THE RIGOROUS PLEADING STANDARDS FOR *SCIENTER*

In Section III, below, we address the Complaint's allegations on a statement-by-statement or category-by-category basis, including why each individual statement does not support an inference of reckless or intentional decision. But taken as a whole, the Complaint's flaws merit dismissal on its face. The first fatal flaw is its failure adequately to plead *scienter*. The Complaint falls short of satisfying the *Tellabs* standard of supplying a "cogent and compelling"

inference that the defendants acted with the requisite state of mind to defraud investors. "A [securities class action] complaint will survive [dismissal at the pleading stage] . . . only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Tellabs*, 551 U.S. at 324.

To conjure up an inference that the defendants acted with *scienter*, the plaintiffs simply juxtapose their version of events with the bald assertion that the defendants "knew" those "facts" and "intentionally" failed to disclose them. According to the plaintiffs, the Company "was not complying with cGMPs"; the Allston Facility was "severely overburdened" and created a "serious risk" that the Company would be unable to supply the market; the Company had "woefully deficient compliance practices"; and the "depth and pervasiveness" of the "woefully deficient compliance practices" made the contamination of its products "inevitable." *See, e.g.*, Compl. ¶ 220(A)-(E). The pleading simply claims these "facts" as gospel and baldly attributes their "non-disclosure" to an "intentional[ ] fail[ure] to inform the market . . . of material information." *Id*. at ¶ 323.

But why? Even if one accepts the plaintiffs' allegations, the Complaint doesn't begin to hint at a motive for any officer of Genzyme to conceal anything from investors. The pleading doesn't describe a benefit that accrued to anyone, or even suggest that the Company was somehow better off by leaving investors in the dark. The document does not point to earnings that were manipulated, stock-based compensation that was obtained or kept, opportunities that were generated or losses that were avoided as a result of any nondisclosure. The only thing the Complaint alleges is that "facts" existed, the defendants "knew" them, and they were not disclosed. But that allegation of "fraud" is tautological: the plaintiffs say that because "facts" weren't disclosed they were "intentionally" concealed. According to the plaintiffs, *any* omission

to publicize "facts" the defendants "knew" *must* have been purposefully concealed — even though the pleading does not point to a single shred of evidence to make the connection.

But that is just faulty logic. The gap in the pleading that omits to connect the dots between ostensible "knowledge" of "facts" and "intentional" deception of investors robs the Complaint of *any* inference of reckless or deliberate nondisclosure. And where *no* inference of either rash or premeditated behavior arises, surely a "cogent and compelling" inference does not exist.

Logic aside, the limited pieces of real information the plaintiffs claim was "concealed" — receipt of the 2008 Form 483, bioreactor failures, delays in approval dates set by the FDA — *were* disclosed by Genzyme (or otherwise was made public) during the putative class period. Contrary to the impression the plaintiffs' generalized allegations strive to create, Genzyme's actions and pronouncements paint a picture of steady disclosure as events warranted — a picture that stands in direct contrast to the story served up in the Complaint. So, for example:

- The Form 483 reflecting observations made by the FDA in mid-October 2008 was disclosed to investors on March 2, 2009, when Genzyme announced that it had received a Warning Letter from the FDA addressing some of those observations.
- On November 17, 2008, the Company disclosed that it received, just days before, a notice from the FDA stating that the PDUFA date for its Lumizyme BLA would be delayed until the end of February 2009.
- On January 13, 2009, the Company disclosed that due to shortages in the supply of Myozyme, it had been working with stakeholder groups (physicians and patients) on a plan to manage supplies of the treatment.
- On January 16, 2009, the EMEA issued a press release noting that Genzyme had experienced manufacturing problems that had contributed to Myozyme supply shortages, and that Genzyme was investigating the cause of those events.
- On June 16, 2009, the Company disclosed that a manufacturing run in one of the 2000L bioreactors in use at its Allston plant had been found, just days before, to have been contaminated by a virus.

The fact that much of the information that Genzyme supposedly "concealed" was in fact made public throughout the course of the putative class period eviscerates any inference that the

defendants deliberately sought to keep that information from the public for more than two-years.[7] Instead, it raises a contrary, non-fraudulent inference which, in the language of *Tellabs*, is plainly more "compelling" than any inference the plaintiffs could hope to raise. Courts frequently find that patterns of repeated *disclosure* during a putative class period undermine the inference of fraudulent intent urged by securities class action plaintiffs. *See Horizon Asset Mgmt., Inc. v. H&R Block, Inc.*, 580 F.3d 755, 763-64 (8th Cir. 2009) (citing company's disclosures and finding that "[t]hese statements do not support an inference that [defendant's officers] intended to deceive the public or acted with severe recklessness. Rather, they portray managers who disclosed known accounting problems and warned that work on their internal controls was continuing."); *Iron Workers Local No. 25 Pension Fund v. Oshkosh Corp.*, 08-CV-797, 2010 WL 1287058, at *21 (E.D. Wis. Mar. 30, 2010) ("[A]ny inference of an intent to deceive is further undermined by the disclosures the company actually made.").[8]

In addition to the stream of public disclosures during the putative class period, Genzyme also engaged in consistent communications with its primary regulators at the FDA and EMEA. The plaintiffs themselves allege that their claims are based in part on Genzyme's correspondence with the FDA, which the plaintiffs purportedly obtained *via* requests made pursuant to the Freedom of Information Act ("FOIA"). *See* Compl. ¶¶ 2, 60, 64. Genzyme routinely communicated with regulators regarding the manufacturing problems it had experienced at Geel and Allston, McL. Decl. Ex. K (EMEA Press Release, Jan. 16, 2009); the shortage of Myozyme and Genzyme's plans for "safeguarding Myozyme supply for infants and children," McL. Decl.

[7] In order to minimize the obvious importance of these disclosures, the plaintiffs grudgingly acknowledge, as they must, that the defendants "made partial disclosures of the existence of some of these serious problems during the latter part of the Class Period . . . ." Compl. ¶ 89.

[8] *See also In re The First Marblehead Corp. Sec. Litig.*, 639 F. Supp. 2d 145, 163 (D. Mass. 2009) (holding that defendant's series of disclosures, in part, negated strong inference of scienter); *Gaines v. Guidant Corp.*, No. 03-CV-892, 2004 WL 2538374, at *13-14 (S.D. Ind. Nov. 8, 2004) (same); *In re Brightpoint, Inc. Sec. Litig.*, No. IP-99-0870, 2001 WL 395752, at *17 (S.D. Ind. Mar. 29, 2001) (same).

Ex. J (Press Release, Jan. 13, 2009); and Genzyme's progress on addressing the FDA's Form 483 observations. McL. Decl. Ex. S (Press Release, Mar. 2, 2009, noting that Genzyme submitted responses on Oct. 31, 2008 and Feb. 23, 2009). The Company's regulatory disclosures also confirm that Genzyme — far from covering up information relating to the various issues raised in the Complaint — was pushing information out. This, too, undermines any inference that the defendants sought to "hide" information with fraudulent intent. After all, once in the hands of regulators, the information was available as appropriate under FOIA to requesting members of the public; it was not confidential information held by Genzyme alone.[9]

It is hard to believe that Genzyme would at once disclose information to regulators, and yet nonetheless set out on a deliberate plan to conceal the same information from the public. And, in fact, Genzyme's disclosures to regulators did lead to public disclosure of relevant information by those regulators. For example, the Complaint insists that the public was unaware of problems with two separate bioreactor runs at the Geel and Allston facilities in 2008. But the EMEA *did disclose* information in a press release based on information provided by Genzyme concerning bioreactor run failures in Allston and Geel. *See* McL. Decl. Ex. K (citing manufacturing problems at Genzyme facilities as contributing causes to potential Myozyme supply shortages and noting Genzyme's investigation).

Just as Genzyme's pattern of public disclosures negates any inference of *scienter*, the regulatory disclosures throughout the putative class period also undermine an inference of

[9] FDA regulations provide for the public disclosure of Form 483s via FOIA request. *See* 21 C.F.R. §20.101(a) (2009) ("All Food and Drug Administration records relating to administrative enforcement action disclosed to any member of the public, *including the person who is the subject of such action, are available for public disclosure at the time such disclosure is first made*. Such records include correspondence with companies following factory inspection, recall or detention requests, notice of refusal of admission of an imported product, regulatory letters, information letters, *Forms FD-483* and FD-2275 furnished to companies after factory inspection, and similar records.") (emphasis added); *see also* 21 C.F.R. §20.103(a) (2009) ("All correspondence to and from members of the public . . . is available for public disclosure."); 21 C.F.R. § 20.103(b) (2009) ("Any such correspondence is available for public disclosure at the time that it is sent or received by the Food and Drug Administration . . . .").

scienter-based fraud. The Complaint purports to describe a two-year cover-up of facts by Genzyme, but nowhere explains why — if the Company intended to keep these matters secret — it made the disclosures it *did* make, when it did. It is not enough for the plaintiffs to allege that the defendants "must" have known and "must" have intended to conceal. Instead, they must raise a "cogent and compelling" or "strong" inference that the defendants acted with the requisite *scienter* to engage in a two-year fraud. Under *Tellabs*, the allegations fail entirely to raise a strong or compelling inference that Genzyme acted with *scienter* to conceal the information described in the Complaint; moreover, the steady pace of affirmative disclosure by Genzyme — both to the public and to regulators — raises a competing counter-inference that Genzyme sought to comply with its obligations at all times. This, alone, justifies dismissal of the Complaint.

II. THE COMPLAINT SHOULD BE DISMISSED BECAUSE THE INFORMATION ALLEGED TO HAVE BEEN "CONCEALED" BY GENZYME IS IMMATERIAL AS A MATTER OF LAW AND GENZYME HAD NO DUTY TO DISCLOSE IT

A second ground for dismissal stems from the lack of a duty to make the disclosures the plaintiffs insist Genzyme should have made. While the Complaint pegs various categories of "omitted" information to particular statements during the class period — arguing that all of the statements were rendered false or misleading because of the omissions — at bottom the plaintiffs' basic claim is that the defendants failed to make disclosures concerning alleged conditions relating to Genzyme's manufacturing operations. Most centrally, the plaintiffs complain that the Company did not disclose its receipt of the October 2008 Form 483 (or the contents of that Form 483) until March 2009; the Company did not disclose its alleged failure to comply with cGMPs; and the Company did not disclose that two bioreactor runs failed in 2008. The reason the plaintiffs seek to pin these alleged "omissions" to affirmative statements is obvious: under the case law, these alleged "facts" are not material and there is no duty to disclose them otherwise.

A. Genzyme Did Not Have A Duty to Disclose Its Receipt of Form 483 "Inspectional Observations" from the FDA

Genzyme received from the FDA a Form 483 in October 2008 containing a number of observations made by FDA inspectors regarding the Allston Facility. The Company did not disclose either the receipt of the form or the specific observations it contained until March 2, 2009, when the Company disclosed that it had received a Warning Letter from the FDA as a follow-up to some of the prior observations. The fact that Genzyme did not disclose the Form 483 observations between October 2008 and March 2009 is perhaps the most frequently repeated allegation in the Complaint.[10] But courts have squarely rejected the claim that companies are required to disclose their receipt of Form 483 observations from the FDA.

Form 483s prominently feature prefatory language stating that they contain only "inspectional observations" that "do not represent a final FDA determination regarding [the company's] compliance." Courts have cited this language, along with similar language in the agency's published guidelines in holding non-actionable the non-disclosure of Form 483s. *See Pub. Pension Fund Group v. KV Pharm.*, No. 4:08-CV-1859, 2010 WL 681443, at *10 (E.D. Mo. Feb. 22, 2010) (noting that "the FDA explicitly states on its website that a Form 483 does not represent the FDA's final determination of a company's compliance").[11] Just like the plaintiffs here, the *KV Pharm*. plaintiffs contended that the defendant company had a duty to disclose *numerous* Form 483s because the forms purportedly confirmed the company's non-compliance with cGMPs. *Compare id.* at *10, *with* Compl. ¶ 259(A)-(B). The district court disagreed and dismissed the claims, holding that "the Form 483s issued to KV only contained

[10] *See* Compl. ¶¶ 11, 12, 100, 103, 105-107, 109, 114, 116, 120, 250, 252, 255, 258, 259, 269.

[11] Notably, the plaintiffs in the *KV Pharm*. case pointed to a series of specific, affirmative statements by the defendant company that "[w]e are currently in material compliance with cGMP." *Id*. at *1-4, 10. No such affirmative statement is at issue here.

observations — not 'a list of cGMP violations' as alleged by lead plaintiffs." *KV Pharm*., 2010 WL 681443 at *10.

The Second Circuit also affirmed the dismissal of a Section 10(b) claim premised on the defendant's failure to disclose the receipt of FDA inspection observations. *See Acito v. IMCERA Group, In*c., 47 F.3d 47 (2d. Cir. 1995). Although the *Acito* plaintiffs alleged that the results of the FDA's inspections of the defendant's facilities "constituted material information and should have been disclosed to the investing public," both the trial and appellate courts disagreed, citing the interim nature of the FDA's observations and noting that "[i]t would be unduly burdensome and impractical to publicly disseminate the results of every inspection of every plant." *Id*. at 52-53.

The *Acito* court also rejected very nearly the same allegation as one the plaintiffs offer here: that the receipt of the Form 483 made it inevitable that the FDA would not approve the Company's pending application relating to a new product. Instead, the Second Circuit held that an interim FDA inspection report does not support an inference that "it was a foregone conclusion" at the time of the report that approval of the subject drug would be denied. *Id*. at 53. The same reasoning is fatal to the plaintiffs' parallel claim that Genzyme somehow knew that its Lumizyme BLA would not be approved once it had received Form 483 observations.

Several courts, including courts in this District, have gone a step further, holding that a company's failure to disclose an FDA *warning letter* — a letter that conveys "the Agency's position on a matter" and typically follows the receipt of a Form 483 when issues are not resolved to the FDA's satisfaction — also is not actionable under Section 10(b), because even a warning letter is merely "informal and advisory." *See Boston Scientific*, 490 F. Supp. 2d at 160-61 & n.113, *rev'd on other grounds, Miss. Pub. Employees Retirement Sys. v. Boston Scientific*

Corp., 523 F.3d 75, 86 (1st Cir. 2008).[12] In *Boston Scientific*, the plaintiff cited FDA "warning letters [that] outlined significant deficiencies or regulatory problems that inspectors discovered at BSC plants," and alleged that Boston Scientific's failure to disclose the letters was materially misleading to investors. *Id*. at 161. The district court disagreed, granting the motion to dismiss in light of the "court's view that the FDA letters were not material and that [the company] had no affirmative duty to disclose them." *Id*. at 161 & n.113; *Anderson v. Abbott Labs*., 140 F. Supp. 2d 894, 902 (N.D. Ill. 2001) (granting motion to dismiss and observing that "[t]here is nothing magical about the warning letter. Although the language sounds ominous, it really is rather boilerplate."), *aff'd sub nom. Gallagher v. Abbott Labs.*, 269 F.3d 806 (7th Cir. 2001). Here, the plaintiffs' allegations concern the non-disclosure (for a period of months) of an "observational" Form 483; it is clear that such information is not material as a matter of law, and that Genzyme had no duty to disclose it.

Addressing nearly identical claims relating to Form 483 disclosure, the *KV Pharm*. court identified a second reason why non-disclosure of a Form 483 is not actionable — because any Form 483 is contained in FDA files and is publicly available via FOIA request. In dismissing an allegation that the defendant corporation misled investors by failing to disclose the receipt of *eight* Form 483s, the *KV Pharm*. court cited (among the reasons) the fact that the Form 483s were publicly available and noted that "'the securities laws require disclosure of information *that is not otherwise* in the public domain.'" *Id*. at *14 (quoting *Sailors v. N. States Power Co*., 4 F.3d 610, 613 (8th Cir. 1993)) (emphasis in original). Thus, for the additional reason that the Form 483s were "readily accessible to the public by submitting a request to the FDA" pursuant

[12] The *Boston Scientific* court cited the FDA's Regulatory Procedures Manual on Warning Letters: "A Warning Letter is informal and advisory. It communicates the Agency's position on a matter, but it does not commit FDA to taking enforcement action." http://www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProceduresManual/UCM074330.pdf. *See* 490 F. Supp. 2d at 161 n.113.

to FOIA, the court held that "[defendants] were under no duty to disclose these documents." *KV Pharm.*, 2010 WL 681443 at *14. The same logic applies here.

B. Genzyme Did Not Have A Duty to Disclose Purported "Non-Compliance" With cGMPs

Plaintiffs insist that Genzyme was required — even prior to its receipt of the FDA Form 483 observations — to disclose that it "was not complying with cGMP at the Allston plant." But the only particularized allegation supporting the alleged deficiencies set forth in the Complaint arises from the Form 483 observations made in October 2008. As noted above, courts have rejected claims that inspectional observations by the FDA by themselves establish violations of cGMP standards. *See* Section II. A., *supra*.

C. Genzyme Did Not Have A Duty to Disclose Purported Manufacturing Difficulties

A third central thrust of the plaintiffs' claims is that Genzyme was required to disclose manufacturing difficulties or alleged "compliance failures" at the Allston Facility.[13] These range from the failure of two bioreactor runs in 2008 to a litany of "deficiencies" (lifted from FDA observations made in the 2008 Form 483), such as "failure to properly maintain equipment," "overloaded facility," "unsterile airflow system," and "lack of adequate training and record keeping." *See* Compl. ¶ 6.[14] But courts have refused to impose a duty on companies to disclose operational or manufacturing setbacks. *See Minneapolis Firefighters' Relief Ass'n v. MEMC Elec. Materials, Inc.*, No. 4:08-CV-1411, 2010 WL 889864, at *5-6 (E.D. Mo. Mar. 8, 2010) (no duty to disclose manufacturing disruptions at two facilities); *In re Ford Motor Co. Sec. Litig.*,

[13] *See, e.g.*, Compl. ¶¶ 250, 251, 259(A)-(B), 269, 287(A), 310(A).

[14] Plaintiffs' five "confidential witnesses" add little if anything to what the Complaint has already lifted from the Form 483. *See* Compl. ¶¶ 63 (2007 contamination at Allston); 66 (chromatography columns); 78, 102 (hiring practices); 82 (Framingham facility); 82 (Framingham testing of raw materials). None of the alleged deficiencies they report amounts to anything Genzyme was required to disclose. Furthermore, one confidential witnesses left Genzyme in 2004 (¶ 66) and another in 2007 (¶ 63), before the class period even began, and two others left Genzyme in 2008 and are not alleged to have worked at Allston (¶ 82).

184 F. Supp. 2d 626, 633 (E.D. Mich. 2001) (no duty to disclose tire problems with Ford Explorer, even though they later gave rise to a recall); *In re N. Telecom Ltd. Sec. Litig.*, 116 F. Supp. 2d 446, 459 (S.D.N.Y. 2000) (no obligation to disclose software product or customer problems); *In re Union Carbide Class Action Sec. Litig.*, 648 F. Supp. 1322, 1327 (S.D.N.Y. 1984) (no duty to disclose risks and defects at chemical plant, despite the fact that they later resulted in industrial accident). Instead, courts have recognized that requiring the disclosure of each manufacturing difficulty or condition "would constitute an overly expansive reading of the federal securities laws, and might encourage corporations to disclose trivial information not necessary for informed decision making." *Union Carbide*, 648 F. Supp. at 1328.

Plaintiffs' contention that the difficulties confronted by the Company were the result of undisclosed "woefully inadequate compliance practices" or a list of "extraordinary, serious and undisclosed problems that plagued Genzyme and its flagship Allston Facility" smack of an effort to manufacture claims after-the-fact from allegations of poor management — allegations courts have long held are not actionable under the federal securities laws. *See, e.g.*, *Santa Fe Indus.*, 430 U.S. at 479 ("We thus adhere to the position that 'Congress by § 10(b) did not seek to regulate transactions which constitute no more than internal corporate mismanagement.'") (quoting *Superintendent of Ins. v. Bankers Life & Cas. Co.*, 404 U.S. 6, 12 (1971)).[15] The result should be no different here.

[15] Courts have relied on *Santa Fe* in dismissing federal securities laws claims which "sound[] more in [allegations of] possible corporate mismanagement, viewed retrospectively, than in fraud." *Union Carbide*, 648 F. Supp. at 1328; *see also First Marblehead*, 639 F. Supp. 2d at 160-61 (relying on *Santa Fe* in dismissing allegations of inadequate internal controls and mismanagement); *Akerman v. Bankworcester Corp.*, 751 F. Supp. 11, 12-13 (D. Mass. 1990) (relying on *Santa Fe* to dismiss claims regarding bank's practices which were directed "more to mismanagement than to misrepresentation"); *In re Citigroup, Inc. Sec. Litig.*, 330 F. Supp. 2d 367, 375 (S.D.N.Y. 2004) (citing *Santa Fe* in finding that claims amounting to "nothing more than a charge that Citigroup's business was mismanaged. Such allegations of mismanagement, even where a plaintiff claims that it would not have invested in an entity had it known of the management issues, are insufficient to support a securities fraud claim under section 10(b).").

III. THE COMPLAINT SHOULD BE DISMISSED BECAUSE THE STATEMENTS CITED IN THE COMPLAINT ARE NOT ACTIONABLE

As demonstrated above, the alleged information the plaintiffs insist Genzyme "concealed" during the class period is not information Genzyme had a duty to disclose. This fact alone justifies dismissal of the Complaint. To avoid this result, the plaintiffs hope to establish that Genzyme had a duty to disclose allegedly "concealed" information because of affirmative statements the Company did make during the class period, statements the plaintiffs allege were rendered "false and misleading" because of the "concealed" information.

A. The Complaint Fails to Allege Any Actionable Misstatement or Omission Regarding Genzyme's Anticipation of FDA Approval of the Lumizyme BLA

About half of the statements alleged to be "false or misleading" consist of substantially similar public statements by Genzyme or its officers regarding the Company's expectations of approval of the Lumizyme BLA, and the timing for that approval.[16] The plaintiffs assert that the identified statements were false or misleading because of a variety of alleged "facts" — including that the Allston Facility was not in compliance with cGMPs and that unspecified "stress" on that plant meant that Genzyme would ultimately not be able to satisfy FDA requirements for Lumizyme approval. *See* Compl. ¶¶ 220, 227, 242-43. These claims fail to state an actionable claim under Section 10(b) of the Exchange Act for several independent reasons, each of which justifies dismissal. First, the plaintiffs themselves acknowledge in the Complaint that "there is no assurance that the FDA will make a determination by any given target PDUFA date, and certainly no assurance that the FDA will actually approve (rather than reject) the new product application by that date." Compl. ¶ 93. Second, the statements fail to

[16] *See* Compl. ¶¶ 216, 217, 230, 235, 237, 239, 240, 246, 250, 255, 258, 264, 266, 269, 270, 275, 276, 277, 280, 290, 294, 295, 297, 298, 302, 305, 306, 308, 312, 316, 318, 319.

satisfy the exacting standards for pleading *scienter*. Third, the statements are forward-looking and shielded by the PSLRA's "safe harbor" and the common law "bespeaks caution" doctrine.

1. Plaintiffs Cannot Have Reasonably Relied on Statements Concerning the Possible Timing of FDA's Approval of Lumizyme

Plaintiffs complain that Genzyme made repeated statements concerning the expected timing of FDA approval of the Lumizyme application. During the putative class period, when the Company described the anticipated timing of FDA action on Lumizyme, it relied upon the so-called PDUFA date — the target date of six months from the date of filing, by which the agency is expected to act on a drug application. The plaintiffs contend that Genzyme's statements regarding the FDA's timing on Lumizyme were false throughout the putative class period, because the FDA failed to approve the Lumizyme BLA on the Company's expected schedule.

But the plaintiffs cannot establish the necessary element of "reasonable reliance" in connection with this central aspect of their claim. The FDA's setting of a PDUFA date is not a guarantee that the agency will act on or before that date; rather, it expresses a goal or target, nothing more, and can be extended.[17] This is widely understood.[18] Indeed the plaintiffs themselves expressly acknowledge that "there is no assurance that the FDA will make a determination by any given target PDUFA date, and certainly no assurance that the FDA will actually approve (rather than reject) the new product application by that date." Compl. ¶ 93.

[17] *See* FDA Amendments Act of 2007, Pub. L. 110-85, § 101(c), Sept. 27. 2007; Letter from Michael O. Leavitt, Secretary of Health and Human Services, to the Honorable John D. Dingell, Chairman, House Committee on Energy and Commerce, Section A: PDUFA IV Reauthorization Performance Goals and Procedures: Fiscal Years 2008 through 2012 (Sept. 27, 2007), available at http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm119243.htm.; 21 C.F.R. § 314.100(a), (c) (2009); Henry Grabowski et al., *Do Faster Food and Drug Administration Drug Reviews Adversely Affect Patient Safety? An Analysis of the 1992 Prescription Drug User Fee Act*, 51 J.L. & Econ. 377, 380-81 (2008).

[18] *See generally* James L. Zelenay, Jr., *The Prescription Drug User Fee Act: Is a Faster Food and Drug Administration Always a Better Food and Drug Administration?*, 60 Food & Drug L.J. 261 (2005) (discussing drug application review goals as FDA response to public and pharmaceutical industry pressure for more efficient drug approval processes).

In this way, the plaintiffs' own allegations *admit* that investors knew there could be "no assurance" of FDA action, or the timeframe for it, and thus confirm that they could not have reasonably relied on any anticipatory statement by Genzyme on that subject. *See Garvey v. Arkoosh*, 354 F. Supp. 2d 73, 82 n.12 (D. Mass. 2005) (dismissing fraud-on-the-market claims where information available to the market prevented reasonable reliance on allegedly misleading statements); *see also Rodriguez-Ortiz v. Margo Caribe, Inc.*, 490 F.3d 92, 96 (1st Cir. 2007) (citing reasonable reliance as an essential element of a Section 10(b) claim). Because the Complaint itself *concedes* that the PDUFA date supplied by the FDA cannot be relied upon as a guarantee of agency action by a certain date, there can be no reasonable reliance in connection with Genzyme's statements relating to the timing of FDA approval of the Lumizyme BLA.

2. Plaintiffs' Allegations Fall Short of the Requirements For Pleading *Scienter*

As argued above, see *supra* Section I, the Complaint fails to supply a strong inference of *scienter*, because the pattern of public and regulatory disclosures by Genzyme during the period fatally undermines *any* inference of fraudulent intent, let alone one that is sufficiently "cogent and compelling" to meet the *Tellabs* test. This is especially true of the many class period statements attributed to the defendants concerning anticipated Lumizyme approval and its timing — statements which comprise the great bulk of the purported "misstatements." In this Section, we address the Complaint's failure to allege *scienter* specifically with regard to these statements.

"The PSLRA requires that the plaintiffs' complaint, 'with respect to each act or omission . . . , state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.'" *N.J. Carpenters Pension & Annuity Funds v. Biogen IDEC, Inc.*, 537 F.3d 35, 44 (1st Cir. 2008) (quoting 15 U.S.C. § 78u-4(b)(2)) (affirming dismissal of securities fraud claim where plaintiffs failed adequately to allege scienter). The required state of

mind for a securities fraud claim is "'a mental state embracing intent to deceive, manipulate, or defraud.'" *Id*. (quoting *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 193 n.12 (1976)). As noted, the Supreme Court has held that the PSLRA's "strong inference" of *scienter* requires something "more than merely plausible or reasonable — it must be cogent and at least as compelling as any opposing inference of non-fraudulent intent." *Tellabs*, 551 U.S. at 314.

Pre-Form 483 Statements. The Complaint cites a number of statements concerning FDA approval of Lumizyme made during the period from October 24, 2007 — the start of the putative class period — to October 10, 2008, the date Genzyme received the Form 483. The Complaint asserts that statements of anticipation as to Lumizyme approval during this period were false because the defendants purportedly "knew" that approval would not be granted due to the Allston Facility "not complying with cGMP," "woefully deficient compliance practices," and other "stress" placed on the plant. *See* Compl. ¶ 220. But nowhere does the Complaint allege with particularity *how* the defendants purportedly knew this information during the relevant period; there is only the bald assertion that they did. As a result, there simply is no basis upon which to draw an inference of *scienter* in connection with these statements, let alone the "strong inference" required by the PSLRA and *Tellabs*. *See Rodriguez-Ortiz*, 490 F.3d at 96 ("[A]s to scienter, not any inference will do: the ultimate inference of scienter must be a strong one.").[19]

Lacking specific facts, the plaintiffs instead resort to conclusory allegations of conditions that purportedly render the statements false: supposed "woefully deficient compliance practices," "rampant [cGMP] violations," and "serious deficiencies at the Allston plant." Compl. ¶¶ 57, 220, 251. But these generalized accusations — devoid of any particularized factual support — simply do not suffice to support a "strong inference" that the defendants knew at any

[19] Moreover, because statements relating to expected Lumizyme approval are forward-looking, as explained in more detail below, the PSLRA requires the plaintiffs to plead facts giving rise to a strong inference of *actual* knowledge, not merely constructive knowledge. *See Praecis*, 2007 WL 951695 at *5. This the Complaint fails entirely to do.

relevant time that the Allston Facility was "violating" cGMPs or that there would be a delay to the Lumizyme BLA approval process.[20] *See KV Pharm.*, 2010 WL 681443 at *10 (granting motion to dismiss Section 10(b) claim where plaintiffs pled no specific facts to show the defendant's cGMP non-compliance).

Statements between Receipt of Form 483 and Complete Response Letter. Plaintiffs also allege that after the Company received the FDA's Form 483 observations in October 2008, its statements on Lumizyme timing and approval continued to be misleading, because the Form 483 allegedly informed Genzyme that Lumizyme approval would be delayed beyond the November 2008 PDUFA date and/or that the BLA would not be approved at all. *See, e.g.*, Compl. ¶¶ 250, 252, 255, 259, 264. Again, plaintiffs allege nothing more by way of particularized fact. The Complaint merely leaps to the conclusion that as a result of the October Form 483, Genzyme "knew" that the Lumizyme BLA PDUFA date would be extended from November 2008 to February 2009 — a "fact" the plaintiffs insist was required to be disclosed. Compl. ¶¶ 335, 336.

This conclusion-alleged-as-fact is absurd. The Form 483 contains no information whatever regarding a change in the PDUFA date. *See* McL. Decl. Ex. A. As the plaintiffs acknowledge, Genzyme did announce on November 17, 2008 — just days after receiving notification from the FDA — that the PDUFA date had been extended. Compl. ¶ 261. And the plaintiffs fail to state any basis upon which Genzyme "knew", prior to receiving the FDA's notification, that the PDUFA date would be extended. The PSLRA requires more than conclusory assertions that a defendant "knew" a fact at an earlier time; it requires particularized allegations showing who knew information and when to support the claim that information was actually withheld with *scienter*. *N.J. Carpenters*, 537 F.3d at 44 ("'Securities actions raise

[20] Plaintiffs also make no attempt at all to allege any facts giving rise to a strong inference of *scienter* that the defendants had actual knowledge at this time that unspecified "stress" on the Allston Facility would later have an impact on the Lumizyme BLA.

questions of what corporate managers knew and *when they knew it.*'" (quoting *Boston Scientific*, 523 F.3d at 86) (emphasis in original). The Complaint here fails entirely on that basis.

Indeed, the plaintiffs simply assume that Genzyme was in a position to know that the cGMP observations and other issues cited in the Form 483 could have any impact on the timing of Lumizyme approval. In fact, the Form 483 observations were not directed at issues related to bioreactors, bioreactor size, or even the contamination risks that eventuated. They instead dealt primarily with "fill and finish" issues that were "downstream" from the bioreactor processes. The plaintiffs misleadingly take observations related to one small aspect of the overall manufacturing process, and escalate them into conclusions about other unrelated aspects of the manufacturing process. That is not logical pleading; it is deceptive pleading instead.

In fact, the defendants had every reason to expect that FDA approval of the Lumizyme BLA would be forthcoming. In late October, Genzyme secured a key vote in support of the clinical effectiveness of Lumizyme from the FDA Advisory Committee. *See* McL. Decl. Ex. C. Further, FDA guidance states that FDA staff is responsible for communicating to applicants "any significant changes in the review timeline" which might be occasioned by "problems identified during facilities inspections."[21] The Complaint fails to allege that the FDA communicated with Genzyme about any purported impact that issuance of the Form 483 would have on the timing of the Lumizyme application review. With no guidance from the FDA that the PDUFA date would be impacted *by the inspection process or the Form 483 observations*, Genzyme reasonably believed that the PDUFA date was not impacted by those factors. *See Fort Worth Employers' Retirement Fund v. Biovail Corp.*, 615 F. Supp. 2d 218, 228 (S.D.N.Y. 2009) ("There is not a single allegation in the Amended Complaint that the FDA ever explicitly warned defendants that

[21] FDA Guidance for Review Staff and Industry: Good Review Management Principles and Practices for PDUFA Products (April 2005), at http://www.fda.gov/dowloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidance/UCM079748.pdf.

they were proceeding with an insufficiently supported application."); *see also Johnson v. Pozen Inc.*, No. 07-CV-599, 2009 WL 426235, at *22-23 (M.D.N.C. Feb. 19, 2009) (relying on FDA guidance to find it more plausible that defendants believed that its drug application would be approved despite negative tests results).

Moreover, as the plaintiffs themselves explicitly acknowledge, the FDA's European regulatory counterpart — the EMEA — had already approved Myozyme at the 2000L scale, and had inspected the Allston Facility in 2008 (and certified the plant for cGMP compliance in July 2008). *See* Compl. ¶ 48 ("Genzyme was able to obtain quick approval from European authorities to sell Lumizyme [manufactured at the Allston Facility] in Europe."). This fact alone demonstrates that it was reasonable for the defendants to believe in the prospects for Lumizyme approval.[22] *See In re AstraZeneca Sec. Litig.*, 559 F. Supp. 2d 453, 471 (S.D.N.Y. 2008) (*scienter* pleading insufficient as to ultimate FDA rejection of drug application because "it [was] not unreasonable for defendants to believe in their product" in light of its approval in Europe).

Having plainly failed to plead any specific factual basis upon which the defendants can be shown to have acted with *scienter*, the plaintiffs here opt for a puzzle-pleading structure that diverts attention from the lack of specific allegations of knowledge. This pattern — alleged misstatements matched only with conclusory omitted "facts" unsupported by specific allegations of particularized information known to the defendants at the time the statements were made — recurs throughout the Complaint. So, for example, the plaintiffs contend that the defendants knew after receiving the October 2008 Form 483 that Lumizyme approval would be delayed or would not occur because of a myriad of supposed "barriers" to approval, including cGMP non-compliance and the risk that such "violations" would lead to contamination at Genzyme's

[22] In fact, as Genzyme publicly disclosed, it had received approval for Myozyme manufactured at the 2000L scale in approximately 40 countries. McL. Decl. Ex. T at 3 (Tr. of Conf. Call, Apr. 21, 2008).

facilities. *See* Compl. ¶ 259. But this is all supposition. As shown above, the receipt of a Form 483 simply does not establish cGMP non-compliance. *See* Section II. A., *supra*.

Moreover, the Complaint nowhere alleges — with particularity or otherwise — a causal link between cGMP issues and the viral contamination Genzyme experienced at its facilities. The Complaint merely contends in the broadest terms that the issues cited in the October 2008 Form 483 have some bearing on the viral contamination that occurred at the Geel and Allston Facilities in late 2008.[23] But a review of the Form 483 shows that its content relates largely to "fill and finish" manufacturing processes "downstream" of the bioreactors where the contamination occurred; nothing in the Form 483 has anything to do with deficiencies at Allston in detecting or preventing viral contaminations. *See* McL. Decl. Ex. A. The plaintiffs have not — and cannot — allege any relationship between the observations raised in the Form 483 (which, as noted above, did not establish cGMP "violations" in any event) and the contamination events suffered at the Geel and Allston Facilities. *See also* Sections II. A., C., *infra*. As there is simply no relationship between the contaminations, which occurred in bioreactors, and the Form 483 observations, relating to different aspects of the manufacturing process, the plaintiffs have not pled sufficient facts to support their fanciful theory that Genzyme somehow "knew" that the Form 483 observations raised a risk that the Company would also experience bioreactor failures.

Post-Complete Response Letter Statements. Addressing the period after February 28, 2009, when Genzyme received the Complete Response Letter and Warning Letter from FDA, the plaintiffs' allegations continue in the same form. The Complaint contends, for example, that statements regarding Lumizyme approval during this period were materially misleading because the defendants purportedly knew, or were reckless in not knowing, that the concerns raised by

[23] *See* Compl. ¶ 259 ("Defendants failed to disclose . . . the materially heightened risk that those [cGMP] violations would lead to contamination or adulterated products at Allston, as had recently occurred (but not been disclosed) at Geel.").

the FDA in the Warning Letter "were ongoing and would not be resolved" by Genzyme's proposed corrective measures nor within the "short time frame" Genzyme described. Compl. ¶ 287. As the Complaint concedes, Genzyme promptly disclosed the receipt of *both* letters. Compl. ¶ 114. The plaintiffs nonetheless advance the loosely drawn allegation that, following the Warning Letter, Genzyme somehow came to know that the problems cited by the FDA would take a longer time to address and that Genzyme's proposed corrective measures would ultimately not work (or would not work within the anticipated time frame).

Again, all of this is supposition. The Complaint simply does not identify facts with any particularity to support an inference — let alone the required *strong* inference — that the defendants' statements concerning Lumizyme approval were made with knowledge that the BLA would not be approved. For example, when the plaintiffs assert that Genzyme knew (but failed to disclose) that the problems in Allston "would not be corrected," *see* Compl. ¶ 287(A), *on its face* the allegation is premised on hindsight. *See id*. ("Moreover, as the FDA *would later conclude*, Genzyme had failed even to implement its own [corrective action] plans . . . .") (emphasis added).[24] Allegations based on hindsight are plainly insufficient to withstand a motion to dismiss. *See First Marblehead*, 639 F. Supp. 2d at 160 ("[The] allegations amount to fraud by hindsight, essentially inferring earlier knowledge based only on the situation that later came to pass, which the First Circuit has consistently rejected.") (internal quotations omitted); *see also In re Discovery Labs. Sec. Litig*., No. 06-1820, 2007 WL 789432, at *5 (E.D. Pa. Mar. 15, 2007) ("The fact that, more than two years later Discovery has not been able to remedy the problems [cited in the Form 483] . . . does not make the earlier statements false or misleading.").

[24] While not essential to resolution of this motion, the notion that Genzyme did not take any corrective action is patently false, a fact that the plaintiffs know from their review of FDA correspondence. *See, e.g*., McL. Decl. Ex. B (Letter to FDA, Oct. 31, 2008) (outlining Genzyme's plan to respond to Form 483 observations); Ex. U (Letter to FDA, Feb. 23, 2009) (follow-up letter to FDA outlining progress); Ex. V at 21 (Form 10-K for 2008, Mar. 2, 2009) (outlining plan and timeline for corrective action and progress toward completion).

This Court considered conceptually similar *scienter* allegations in *In re Praecis Pharms. Inc., Sec. Litig.*, 2007 WL 951695. In that action, the plaintiffs contended that the defendant's optimistic statements regarding the market for its new product were materially misleading because the defendant purportedly knew that the sales goals it set were unlikely to be achieved and that the pricing structure for the product would ultimately prevent the company from attaining those sales goals. *Id*. at *11-12. In dismissing the Section 10(b) claim for failure to plead *scienter*, the Court stated:

> [I]t is not reasonable to think that the defendants intentionally launched the Company's flagship product with what they recognized was a flawed pricing structure, as if they were more interested in fooling the stock market in the short term than succeeding in the product market in the long run.

Id. at *12. The same reasoning applies with equal force here, where the plaintiffs urge the unreasonable inference that Genzyme somehow (nowhere explained) knew that the Lumizyme BLA was doomed and that the product would never make it to market, yet continued to advise investors that approval was expected imminently. As in *Praecis*, it would be unreasonable to think that Genzyme was more interested in "fooling the stock market in the short term" than in seeing Lumizyme approved and released to the market.[25] This is especially so given that Genzyme *did* disclose information on the FDA's timing and decisions throughout the period.

Other cases echo this Court's approach in *Praecis*, where plaintiffs contended that a company's prospective statements of positive prospects for a new drug were false or misleading under Section 10(b). For example, in *AstraZeneca*, the plaintiffs alleged that statements regarding the company's anticipation of FDA approval of Exanta, a drug in late-stage clinical

[25] Indeed, while securities fraud plaintiffs often cite insider stock sales as a means of establishing an inference of *scienter*, the plaintiffs advance no such allegations here. The implausibility of the *scienter* inference the plaintiffs urge is nowhere more evident than in the pervasive lack of any explanation of *why* the defendants would have engaged in the supposed elaborate deception.

trials, were materially misleading because the company purportedly "knew" when it made the statements that approval was unlikely. 559 F. Supp. 2d at 456. The district court noted that:

> [I]f the management of the company releases positive reports about the drug to the public along the way which the management honestly believes to be true, and where there is no reckless disregard for truth, then that is not securities fraud, even though at a later point some event occurs which prevents the marketing of the drug or makes it necessary to take the drug off the market.

Id. at 470-71 (dismissing for failure adequately to allege *scienter* where the complaint contained "nothing whatever to indicate that the statements made [about Exanta's prospects for FDA approval] did not reflect the honest belief" of management). The same result should obtain here; where the Complaint contains "nothing whatever" to indicate that "there was a consensus of the management" that the issues identified by the FDA would take longer to resolve than Genzyme then anticipated or that the Lumizyme BLA was "unlikely to be approved." *Id.*

3. The PSLRA Safe Harbor and the Common Law Bespeaks Caution Doctrine Preclude Liability

Finally, *all* of the alleged misstatements relating to Lumizyme approval are forward-looking and fall within the PSLRA's safe harbor (and also are subject to the protections afforded by the safe-harbor's common law predecessor, the "bespeaks caution" doctrine). For this additional reason, they are not actionable under Section 10(b). *See* 15 U.S.C. § 78u-5 (2010).

The PSLRA safe harbor extends immunity from securities fraud claims to certain types of statements that "speak predictively of the future." *In re Stone & Webster, Inc., Sec. Litig*., 414 F.3d 187, 195 (1st Cir. 2005); *see also* 15 U.S.C. § 78u-5(i)(1) (2010) (defining "forward-looking statement"). Such statements are protected where: (1) the forward-looking statement is identified as such and is "accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement"; or (2) the statement is not material; or (3) the plaintiff fails to establish that

the defendant made the statement with actual knowledge of its false or misleading nature. 15 U.S.C. § 78u-5(c)(1) (2010).[26]

Among other categories, the PSLRA safe harbor applies to "a statement of the plans and objectives of management for future operations, including plans or objectives relating to the products or services of the issuer[.]" 15 U.S.C. § 78u-5(i)(1)(B) (2010). This is precisely the type of statement cited by the plaintiffs regarding Genzyme's plans for approval of the Lumizyme BLA. *See, e.g.*, Compl. ¶¶ 217 (citing Oct. 24, 2007 statement that "we expect the approval [of the Lumizyme BLA] to occur in the first quarter of next year"); 230 (citing Apr. 21, 2008 conference call stating "we are now predicting the FDA action by the end of this year" and "now expect that commercialization of the 2000-liter material for late-onset patients in the United States will start in the first quarter of next year"); 258 (citing November 7, 2008 statement that "We expect the FDA to act on the [Lumizyme] BLA by November 29, 2008"); 264 (citing January 13, 2009 press release statement that the Company "expects to . . . [o]btain regulatory approvals for larger-scale production of Myozyme" in 2009); 290 (citing March 24, 2009 statement that "[w]e anticipate U.S. approval of . . . Lumizyme, in mid-2000 [sic]").[27] These statements plainly are forward-looking under the statute. *See In re Medimmune, Inc. Sec. Litig.*, 873 F. Supp. 953, 964 (D. Md. 1995) ("Mere expressions of hope or expectation regarding

[26] The common law "bespeaks caution" doctrine was the predecessor to the PSLRA safe harbor and also applies to preclude liability for securities fraud where a forward-looking statement is accompanied by meaningful cautionary language. *See, e.g.*, *Fitzer v. Sec. Dynamics Techs.*, 119 F. Supp. 2d. 12, 31 (D. Mass. 2000) (granting motion to dismiss 10(b) claim under common law "bespeaks caution" doctrine and citing *Shaw v. Digital Equip. Corp.*, 82 F.3d 1194, 1213 (1st Cir. 1996)). Herein, where the defendants reference the PSLRA safe harbor, such reference should be read to include the parallel common law doctrine as well.

[27] For the Court's benefit, all of the Lumizyme-related forward-looking statements are identified and collected in Attachment 2.

future approval, not worded as guarantees, are not actionable."); *In re PLC Sys. Inc. Sec. Litig.*, 41 F. Supp. 2d 106, 117-18 (D. Mass. 1999) (same).[28]

In addition to their forward-looking nature, each of the statements was accompanied by meaningful cautionary language on the risk that the FDA might *not* approve Lumizyme, or might not do so on the time frame then anticipated by the Company.[29] Accordingly, the PSLRA safe harbor shields all of the alleged misstatements regarding Lumizyme approval from Section 10(b) liability. *See Baron v. Smith*, 380 F.3d 49, 53-54 (1st Cir. 2004) (forward-looking statement accompanied by meaningful cautionary language held not actionable under Section 10(b)).

Thus, as shown above, the alleged misstatements concerning anticipated Lumizyme approval are not actionable, because (i) the plaintiffs cannot establish that they reasonably relied on Genzyme's statements concerning anticipated Lumizyme approval; (ii) the Complaint fails to allege fraudulent intent sufficient to supply any inference — much less a *compelling* inference — of *scienter*; and (iii) Genzyme's statements concerning anticipated Lumizyme approval are not actionable under the PSLRA safe harbor for forward-looking statements, as well as the "bespeaks caution" doctrine. This Court should dismiss all claims based on such statements.

---

[28] This is not a case where Genzyme guaranteed FDA approval of Lumizyme. As Attachment 2 shows, Genzyme merely expressed its hope and expectation for approval. Each of Genzyme's statements was accompanied by cautionary language that specifically identified the uncertainties inherent in the Lumizyme approval process. These cautions, coupled with Genzyme's expressions of anticipation, make clear that Genzyme did not portray Lumizyme approval as a "when not if" proposition. *Compare In re Transkaryotic Therapies, Inc. Sec. Litig.*, 319 F. Supp. 2d 152, 160-61 (D. Mass. 2004) ("[S]tatements, such as 'We believe the approval of Replagal in the U.S. remains a when not if proposition' . . . arguably do not fall within the safe harbor provisions."), *with In re Bristol-Myers Squibb Sec. Litig.*, 312 F. Supp. 2d 549, 558 (S.D.N.Y. 2004) (refusing to find statements that defendants were "very positive about the approval prospects for this drug" and did not "think it's likely at all that this drug won't get approved" constituted guarantees actionable under the securities laws). This is also not a case where Genzyme had information that seriously undermined the accuracy of its statements. *See, e.g.*, McL. Decl. Ex. C (Press Release, Oct. 22, 2008) (describing FDA Advisory Committee's 16-1 vote in support of Lumizyme's efficacy as treatment for Pompe disease); *cf. In re Amylin Pharms., Inc. Sec. Litig.*, No. 01-CV-1455, 2003 WL 21500525, at *8 (S.D. Cal. May 3, 2003).

[29] For the Court's benefit, citations to the relevant, extensive cautionary statements provided by Genzyme alongside the statements cited in the Complaint are collected in Attachment 2.

B. Statements Regarding FDA Re-Inspection Are Not Actionable

The Complaint contends that the defendants misled investors by stating during a March 2, 2009 conference call that the Company did not expect that the Lumizyme BLA process would require re-inspection of the Allston Facility, when the process ultimately *did* require a second inspection. *See* Compl. ¶¶ 281, 287(D); *see also id.* ¶¶ 307, 310(D). But in the same paragraph accusing the defendants of falsely representing that re-inspection would not be necessary, the Complaint directly quotes Mr. Bamforth explaining that while the Company did not anticipate re-inspection, "'[c]learly, the FDA has the liberty if they choose to do a follow-up to require that.'" Compl. ¶ 281. Moreover, as the plaintiffs acknowledge, there can never be any "assurance" of how or when the FDA will act. Compl. ¶ 93. Because the defendants cautioned of the chance of re-inspection, the statements simply are not materially misleading — no investor could cite the statement as a guarantee of no re-inspection — and the statement provides no good faith basis for a securities fraud claim.[30]

C. The Complaint Fails to Allege Any Actionable Misstatement or Omission Regarding the Contamination Events Experienced in 2008 at Genzyme's Geel and Allston Facilities

In September 2008, Genzyme was performing process validation runs at the Geel Facility, which was built to manufacture Myozyme at the 4000L scale. The facility was not yet approved for commercial production, and thus its product was not then commercially available to patients. Genzyme observed a rapid decline in cell productivity during one of several PV runs, and, consistent with its normal practice, commenced an investigation into the cause. In the meantime, the plant continued forward to complete the process of gaining regulatory approval (and secured the first such approval in February 2009). In November 2008, Genzyme observed

[30] Moreover, the plaintiffs have not begun to plead how the defendants purportedly *knew*, as of March 2, 2009, that re-inspection would later be required by the FDA.

at its Allston Facility a decline in cell productivity during a bioreactor run that was involved in the manufacturing of Myozyme at the 2000L scale (or Lumizyme, as it is called in the U.S.). Genzyme also commenced an investigation into the cause of this second event.

Plaintiffs assert that Genzyme should have disclosed these two events — which Genzyme later determined had been caused by viral contamination — at the time they occurred, and they premise the claim on the theory that these "events" purportedly constrained drug supply, negatively impacted the Lumizyme BLA, and "foreshadowed" future problems at the Allston Facility. Omitting them, according to the Complaint, rendered false or misleading nearly every disclosure Genzyme made between mid-September 2008 and June 16, 2009.[31]

While Genzyme did not disclose the events themselves until it had more information concerning their cause — which Genzyme was entitled to do[32] — the Company did disclose the *impact* those events had on drug supply. Even prior to Fall 2008, Genzyme had cautioned of tight Myozyme supply through the First Quarter of 2009. *See* Compl. ¶¶ 109, 131, 137, 264, 270, 296. Shortly after the two events, in January 2009, Genzyme disclosed that it had been working with stakeholder groups in the Myozyme community (including physicians and patient organizations) on a Supply Management Plan to preserve supplies of the therapy and prioritize patients with particularly acute therapeutic needs. *See* McL. Decl. Ex. J at 4 (Jan. 13, 2009 press release stating that supplies of Myozyme would be "so tight that there is a risk of delays in order fulfillment and consequent potential interruptions in therapy"); Compl. ¶ 264.

Meanwhile, European regulators disclosed information concerning the two events in Geel and Allston. In January 2009, the EMEA issued its own public statement concerning Genzyme's

[31] *See* Compl. ¶¶ 245, 250, 251, 256, 259(C)-(D), 266, 272(B), 276, 286, 291, 296, 298, 300, 310(A), (D)-(E).

[32] *See Higginbotham v. Baxter Int'l, Inc.*, 495 F.3d 753, 761 (7th Cir. 2007) ("Taking the time necessary to get things right is both proper and lawful. Managers cannot tell lies but are entitled to investigate for a reasonable time, until they have a full story to reveal.").

Supply Management Program. In that public release, the EMEA addressed the implications of the tight supply of Myozyme; clearly stated that Genzyme had experienced problems at some of its manufacturing facilities; and also disclosed Genzyme's ongoing investigation into the cause of those events. *See* McL. Decl. Ex. K.[33] The Complaint entirely ignores the fact that the EMEA — like the FDA, a key regulator — released news of the production problems, as well as the investigation Genzyme was conducting, and thus ignores that the available information concerning the two events was made public shortly after they occurred. The Complaint also ignores Genzyme's disclosures concerning the Myozyme supply constraints allegedly caused, in part, by the Allston event, instead blithely asserting that the information was "concealed."

The Company disclosed the results of its investigation of the 2008 Geel and Allston events — in particular, the fact that both had been the result of contamination by the same virus — on June 16, 2009 — only *after* its investigation had concluded. *See* McL. Decl. Ex. L (Press Release, June 16, 2009) ("Genzyme has *now* confirmed that this virus was the cause of declines in cell productivity at its Allston and Geel facilities in two previous instances in 2008 . . . ." (emphasis added)).[34] The June 16 press release also announced the decline in cell productivity in a *third* bioreactor run — this one involving a bioreactor in Allston producing Cerezyme — and cited the Company's conclusion that all three events had been caused by the same type of virus. *See* McL. Decl. Ex. L (stating that Genzyme had identified the presence of the virus in connection with the third bioreactor event "over the weekend"); Compl. ¶ 139.

[33] In its Form 10-K for 2008, Genzyme also disclosed the write-off it took of material from the incomplete PV run at Geel. *See* Compl. ¶¶ 109, 266, 298; McL. Decl. Ex. V at F-23, F-29, F-118 (Form 10-K for 2008, Mar. 2, 2009).

[34] On a June 24, 2009 conference call cited by plaintiffs for other purposes, one of the defendants clearly stated that "it was only as a result of a six month long investigation that we were able to create the specific PCR [test], which allows us to isolate and identify this virus." McL. Decl. Ex. M at 4. This confirms that Genzyme's investigation lasted into the Spring of 2009. The plaintiffs do not allege that this statement was false in any way.

Against this record — which establishes that Genzyme's investigation concluded in Spring 2009 — no alleged fact supports an inference that Genzyme became aware at an earlier time that a virus had caused the two events. Yet the Complaint is premised on the bald allegation that Genzyme was required to disclose the viral contamination long before Genzyme could have done so. *See, e.g.*, Compl. ¶ 245 (alleging failure to disclose "contamination" after it occurred). In order to adequately plead *scienter*, the plaintiffs were obligated to plead facts from which one could draw a strong inference that Genzyme knew material information and withheld that information with "either conscious intent to defraud or a high degree of recklessness." *ACA Fin. Guar. Corp. v. Advest, Inc.*, 512 F.3d 46, 58 (1st Cir. 2008) (internal quotations omitted). Instead, the plaintiffs simply insist that Genzyme was required to disclose the viral contamination earlier, without providing any basis for the claim that Genzyme could have done so. This is not enough to survive dismissal. *See N.J. Carpenters*, 537 F.3d at 45 (explaining that a statement or omission "cannot be intentionally misleading if the defendant did not have sufficient information at the relevant time to form an evaluation that there was a need to disclose certain information and to form an intent not to disclose it."); *Isham v. Perini Corp.*, 665 F. Supp. 2d 28, 35 (D. Mass. 2009) (dismissing Section 10(b) claim for inadequate *scienter* pleading where complaint failed to plead that any defendants "were even aware of" the supposed significance of the information allegedly withheld) (quotations omitted).

In all other respects, too, the plaintiffs' allegations concerning the Geel and Allston events fail to satisfy the PSRLA and Fed. R. Civ. P. 9(b). As noted above, the PSLRA requires that allegations made on information and belief, as these are, must "state with particularity all facts on which that belief is formed." 15 U.S.C. § 78u-4(b)(1). The Complaint fails even to try to meet this standard. For example, the plaintiffs loosely suggest that the 2008 Geel event bore

some relationship to the 2008 Form 483, Warning Letter, and Complete Response Letter, but no particular fact is alleged as a basis for that (erroneous) contention. Even a cursory review of these pieces of FDA correspondence show that the agency's inspection of Allston had nothing to do with the Geel event. *See* McL. Decl. Exs. A, E, F. Moreover, nowhere in any of the FDA's correspondence — including the Complete Response Letter indicating that the Lumizyme BLA would not be approved at that time — is the Geel contamination (or *any* viral contamination) even referenced. *See* McL. Decl. Ex. F. In the same way, the Complaint asserts that the 2008 Allston contamination established cGMP "violations" and showed that the facility was not in compliance with cGMPs. *See* Compl. ¶¶ 105, 242, 259(B). But the FDA's Warning Letter and Complete Response Letter regarding cGMPs do not even *mention* the 2008 Geel or Allston events. *See* McL. Decl. Exs. E, F.

Because the plaintiffs have failed to satisfy the requirements of 9(b) and the PSLRA with respect to pleading *scienter*, and because the plaintiffs have failed to establish that Genzyme was required to disclose the 2008 contaminations before it did or that Genzyme was even capable of doing so, the Court should dismiss all claims stemming from the Fall 2008 contamination events.

D. The Complaint's Allegations Relating to Defendants' General Statements of Optimism Are Non-Actionable Puffery

The Complaint identifies approximately ten generalized, optimistic statements made by Genzyme or its officers or directors about the Company's prospects that the plaintiffs contend were false or misleading in light of challenges that the Company later encountered. *See, e.g.*, Compl. ¶¶ 223 (statement that the Company had an "outlook for strong growth," and that the Company felt "bullish" regarding the future), 228 (statement that the Company's strong growth "positioned the company well for 2008"), 237 (statement characterizing the second quarter of 2008 as "strong and highly productive" and noting that the Company "set in place a number of

catalysts that will drive near-term growth").[35] But it is well-settled that such vague expressions of optimism and rosy affirmations are immaterial as a matter of law, not relied upon by investors, and, consequently, not actionable under the securities laws. *Shaw*, 82 F.3d at 1217. This rule applies to both statements about an issuer's current state of affairs and statements about its future prospects. *In re Boston Tech., Inc. Sec. Litig.*, 8 F. Supp. 2d 43, 54 (D. Mass. 1998). Such statements are not actionable because reasonable investors would neither rely on, nor deem material, vague expressions of optimism that amount to nothing more than puffery. *See Shaw*, 82 F.3d at 1217 ("In particular, courts have demonstrated a willingness to find immaterial as a matter of law a certain kind of rosy affirmation commonly heard from corporate managers and numbingly familiar to the marketplace . . . ."); *Praecis*, 2007 WL 951695 at *8 ("Courts have routinely held such statements, generally optimistic but lacking in certainty or specifics, to be transparent 'puffery,' and therefore immaterial as a matter of law.").[36]

E. The Complaint Fails to Allege Any Actionable Misstatement or Omission Regarding Earnings Guidance or Revenue Expectations

The Complaint cites nearly every statement Genzyme made relating to financial projections or performance during the Putative Class Period, and asserts — without ever providing specific support for the contention or alleging how the speaker purportedly *knew* the statement would prove false — that such statements were materially misleading because the

[35] *See also* Compl. ¶¶ 217, 224, 252, 254, 263, 267, 292.

[36] Here, the statements the plaintiffs cite — referencing "confidence" that the company is "well-positioned," with a "strong outlook" and "growth potential" — are precisely the sort of loose expressions of optimism that courts have held to be non-actionable puffery. *See Kenney v. State St. Corp.*, No. 09-CV-10750, 2010 WL 938333, at *9 (D. Mass. Mar. 15, 2010) (statement that business was "very strong" "is precisely the sort of corporate macro statement that courts have deemed nonactionable"); *Orton v. Parametric Tech. Corp.*, 344 F. Supp. 2d 290, 301 (D. Mass. 2004) (company was "positioned . . . for long-term growth"); *In re Parametric Tech. Corp. Sec. Litig.*, 300 F. Supp. 2d 206, 220 (D. Mass. 2001) (company was "well positioned for growth"); *In re Chipcom Corp. Sec. Litig.*, No. 95-11114, 1996 U.S. Dist. LEXIS 22257, at *40-43 (D. Mass. Apr. 29, 1996) ("strong"); *In re PDI Sec. Litig.*, No. 02-211, 2006 WL 3350461, at *22 (D.N.J. Nov. 16, 2006) (company felt "confident"); *In re Syntex Corp. Sec. Litig.*, 855 F. Supp. 1086, 1095 (N.D. Cal. 1994) ("we're doing well and I think we have a great future," "business will be good this year . . . we expect the second half of fiscal 1992 to be stronger than the first half, and the latter part of the second half to be stronger than the first," and "everything is clicking").

Company had not disclosed, or factored into its financial guidance, the purportedly poor "condition" of the Allston facility, the cGMP "violations," and the "fact" that the contaminations at the Geel and Allston Facilities constrained supplies of Myozyme, Cerezyme, and Fabrazyme.[37] In addition, the Complaint's mammoth section detailing the purportedly "false or misleading statements" is replete with statements regarding financial performance, but lacking in any specific allegation as to how the statement is alleged to be false. *See, e.g.*, Compl. ¶¶ 233 (citing Apr. 23, 2008 Press Release and Form 8-K reporting growth of total revenue over the first quarter of 2008, reasons for revenue growth, and an increase in demand and sales of Myozyme, Cerezyme, and Fabrazyme); 257 (citing Nov. 7, 2008 Form 10-Q statements regarding growth in Cerezyme and Fabrazyme sales).[38] These statements represent the apotheosis of the plaintiffs' efforts to pin allegedly omitted information Genzyme had no independent duty to disclose[39] to wholly unassociated affirmative statements, in hopes of arguing that Genzyme's duty to disclose arose from the need to make these affirmative statements "not misleading."

None of Genzyme's financial projections or statements regarding earnings guidance is actionable. This is so, first, because the statements qualify for the PSLRA's safe harbor for forward-looking statements. The portion of the PSLRA defining the contours of the safe-harbor includes, among examples of forward-looking statements, statements "containing a projection of revenues, income (including income loss), earnings (including earnings loss) per share, capital

[37] *See* Compl. ¶¶ 223, 224, 235, 249, 254, 255, 261, 264, 266, 268, 270, 275, 276, 290, 297 (citing financial projections); Compl. ¶¶ 220, 227, 236, 241, 259, 262, 265, 272, 287, 300 (purporting to explain why statements are alleged to have been false or misleading)

[38] There are at least eight examples of paragraphs in the "False and Misleading Statements" section that contain *only* this type of retrospective report on financial performance that the plaintiffs do not even assert were inaccurate. *See* Compl. ¶¶ 218, 222, 225, 233, 234, 257, 284, 293. Eleven other paragraphs contain similar historical financial statements, which the plaintiffs fail allege were false, in addition to other statements. *See* Compl. ¶¶ 216, 237, 238, 240, 249, 251, 263, 267, 268, 291, 298.

[39] *See* Section II, *supra* (addressing disclosure obligations arising from Form 483s, FDA warning letters and alleged cGMP violations).

expenditures, dividends, capital structure, or other financial items." 15 U.S.C. § 78u-5(i)(1)(A) (2010). The revenue and earnings guidance statements alleged in the Complaint fall squarely into this category — Genzyme offered forecasts of future performance that were consistently couched in terms of what Genzyme "expected" or "anticipated."[40] Such language is typical of forward-looking earnings and revenue projections shielded by the statutory safe harbor. *See In re Smith & Wesson Holding Corp. Sec. Litig.*, 604 F. Supp. 2d 332, 341 (D. Mass. 2009) (holding that the PSLRA safe harbor protected defendants' statements regarding "anticipated sales, income, income per share . . . [and] capital expenditures" because they were accompanied by cautionary language); *In re Ibis Tech. Sec. Litig.*, 422 F. Supp. 2d 294, 310-13 (D. Mass. 2006) (holding that statements regarding defendant's "prospects for booking one to three implanter orders in 2003" were non-actionable forward looking statements); *First Marblehead*, 639 F. Supp. 2d at 162 (holding that defendant's "projections of revenues from the additional structural advisory fees and residual interests" were non-actionable forward-looking statements); *see also Praecis*, 2007 WL 951695 at *9 (finding statements regarding estimates of a drug's "revenue opportunity" were forward-looking). Also, as the safe-harbor requires, each statement was accompanied by meaningful cautionary language citing earnings and revenue guidance statements as subject to specific risks and uncertainties.[41] The plaintiffs simply cannot state a valid Section 10(b) claim based on forward-looking revenue projections accompanied by appropriate cautionary language.

The Complaint also fails to allege *scienter* with respect to these statements. Nowhere does the Complaint purport to explain whether or how the defendants knew — at the time they

[40] For the Court's benefit, all of the alleged statements cited in the Complaint addressing Genzyme earnings reports and revenue guidance are identified and collected in Attachment 3.

[41] For the Court's benefit, citations to the relevant, extensive cautionary statements provided by Genzyme alongside the earnings and revenue guidance disclosures cited in the Complaint are also collected in Attachment 3.

made any of the identified statements regarding financial results or guidance — that the Company's performance would fall short of the projections given. Instead, the plaintiffs baldly assert that the projections were all false or misleading throughout the putative class period, because they did not take into account the allegedly poor "condition" of the Allston facility, the Company's cGMP "violations," and the "fact" that the 2008 events at the Geel and Allston Facilities constrained drug supplies. Compl. ¶¶ 220, 227, 236, 241, 259, 262, 265, 272, 287, 300. *None* of these theories is supported by factual allegations that could give rise to an inference — strong or otherwise — that the defendants knew that any particular projections or guidance were unattainable. *See Praecis*, 2007 WL 951695 at *10 (simply alleging that the company did not take certain information into account is not enough to state a claim). As an example, the Complaint posits that "the condition of the Allston plant . . . jeopardized the Company's ability to produce sufficient product to meet its projections." Compl. ¶ 259. This is plainly insufficient to state an actionable Section 10(b) claim, because the plaintiffs make no attempt to plead *who* knew *what* specific information about the Allston Facility that made it clear that revenue projections were unattainable, and *how* and *when* such information came to be known. *See N.J. Carpenters*, 537 F.3d at 48-49 (affirming dismissal for lack of scienter where plaintiff failed to plead *when* defendant purportedly knew about problems with its new drug and *how* defendants would know that such information presented a material problem). The plaintiffs simply have not — and cannot — state a claim premised on Genzyme's financial guidance during the putative class period.

F. The Complaint Fails to Allege Any Actionable Misstatement or Omission Regarding Cerezyme or Fabrazyme

The Complaint identifies two statements regarding the prospects for Cerezyme and Fabrazyme that the plaintiffs contend were false or misleading because Genzyme purportedly knew that it could not satisfy the markets for these drugs. *See* Compl. ¶¶ 219, 268.

First, on October 24, 2007, Genzyme's Chief Executive Officer, Mr. Termeer, stated during an earnings conference call that, for existing Cerezyme patients, "'we don't expect there to be, given the very long term extremely solid experience that we have around Cerezyme to be any particular reason for patients to shift or to change . . . .'" Compl. ¶ 219. This statement was made fully one year prior to the 2008 events in Geel and Allston, one year prior to the receipt of the October 2008 Form 483 from FDA, and 20 months prior to the events in Allston announced in June 2009 that first had any impact at all on Cerezyme production. Yet, the plaintiffs contend that this forward-looking statement was false or misleading, citing all of the same reasons and pegged to nothing more than the plaintiffs' insistence that Genzyme "knew" all of it.[42]

In this respect, plainly, the Complaint fails to satisfy the heightened pleading standards required by the PSLRA (as well as *Tellabs*). *See Stone & Webster*, 414 F.3d at 205-206 ("[T]he requirement [of particularity] is not satisfied by a pleading which simply asserts that the defendant knew of the falsity."); *see also* Section I *supra*. Paragraph 220(C), for example, claims the statement is false because Genzyme was aware of conditions that made it certain that FDA approval of Lumizyme could not be achieved, despite the fact that the Lumizyme BLA was

[42] *See* Compl. ¶ 220 (asserting that the statement was false or misleading because Genzyme was: not in compliance with cGMPs, was only able to maintain growth for its products by "overburdening" its Allston Facility, was diverting manufacturing capacity away from Cerezyme and Fabrazyme to manufacture Myozyme, was engaging in unspecified "practices" making contamination or FDA action "inevitable," and because patients would have to switch to competitors' products if Genzyme could not supply the market with its own products).

not submitted until May 2008 — seven months *after* the statement in question even was made. *Scienter* cannot be alleged by hindsight. *See First Marblehead*, 639 F. Supp. 2d at 160.[43]

Still another statement cited by the plaintiffs regarding Cerezyme and Fabrazyme is the set of forward-looking projections for 2009 sales presented by the Company's Chief Financial Officer, Michael Wyzga, during a February 11, 2009 earnings conference call. *See* Compl. ¶ 268. Again, the plaintiffs allege that these statements were false or misleading for the same reasons repeatedly cited throughout the Complaint, *i.e.*, that Genzyme failed to disclose cGMP "violations," receipt of the Form 483, the occurrence of the contamination events in Geel and Allston in 2008, that the Allston Facility was "overburdened," and that it could not manufacture sufficient Cerezyme or Fabrazyme to meet demand. *See* Compl. ¶¶ 259, 272.

But here, too, the Complaint fails — in all of the same ways that the defendants have articulated throughout this memorandum — to allege any specific facts that would support a strong inference of any defendant's actual knowledge *on February 11, 2009* that Cerezyme and Fabrazyme sales would *later* fall short of the projections announced that day. It was not until four months later, in June 2009, in response to the May 2009 Allston contamination, that Genzyme announced it would close the Allston Facility for decontamination, and that those actions would have a material impact on anticipated Cerezyme and Fabrazyme sales. *See* McL. Decl. Exs. L, SS; Compl. ¶¶ 13, 151. Apart from the usual hash of conclusory allegations offered by the plaintiffs to show what the defendants purportedly "knew" at the time the

[43] Mr. Termeer's October 2007 statement regarding Cerezyme patients also was a forward-looking statement relating to guidance for 2011 that was accompanied by meaningful cautionary language. *See* McL. Decl. Ex. X at 3 (Tr. of Earnings Conf. Call, Oct. 24, 2007) (at the beginning of the call, Genzyme's Vice-President for Investor Relations warned investors, "On this call we will discuss Genzyme's future financial outlook and business plans and strategies. We will be making forward-looking statements including our non-GAAP earnings estimates and growth rates for the next five years, our product development plans and regulatory action estimates including for . . . Myozyme manufacturing. These forward-looking statements are subject to a number of risks and uncertainties and our actual results may differ materially. Please refer to the June 30, Form 10-Q on file with the SEC for more information."). Thus, it also falls within the PSLRA's safe harbor and cannot serve as the foundation for a securities fraud claim. *See* Section III. E., *supra*.

statement was made — *i.e*., that the Allston Facility was in violation of cGMPs; that the Company had "overburdened" that facility; the alleged "depth and pervasiveness" of the Company's "woefully deficient compliance practices" in Allston — the Complaint offers no specific *facts* to suggest that the February 2009 Cerezyme and Fabrazyme projections were not fully supported at the time. In this respect, the allegation as to the Company's February 2009 Fabrazyme and Cerezyme guidance fails to satisfy *scienter* pleading requirements.

Plaintiffs' claim regarding the February 11, 2009 Cerezyme and Fabrazyme projections also fails because the statement was forward-looking and accompanied by meaningful cautionary language. *See* McL. Decl. Ex. EE at 3 (Tr. of Earnings Conf. Call, Feb. 11, 2009).[44] As discussed in Section III. E., *supra*, these statements are subject to the PSLRA safe harbor, and therefore cannot serve as the basis for a Section 10(b) claim.

G. The Complaint Fails to Allege Any Actionable Misstatement or Omission Regarding Genzyme's Decisions on the Marketing of Lumizyme (2000L)

Plaintiffs allege that Genzyme failed to disclose a March 2009 "internal decision" to meet United States Myozyme demand with 4000L product produced at Geel rather than continuing to pursue FDA approval 2000L Lumizyme. The plaintiffs contend that the Company's failure to disclose that decision rendered its statements regarding Lumizyme plans materially misleading. *See* Compl. ¶¶ 280, 283, 318, 320. But none of the statements identified by the plaintiffs can support a viable Section 10(b) claim.[45]

---

[44] At the beginning of the February 11, 2009 call, Genzyme's Director of Investor Relations cautioned investors, "On this call we will be discussing Genzyme's future financial outlook, business plans and strategies and we will be making forward-looking statements including discussing our earnings, revenue and expense forecast, our development and regulatory approval plans and estimated timetables for several products and development programs including alglucosidase alfa . . . . These forward-looking statements are subject to a number of risks and uncertainties that may cause our actual results to differ materially. Please refer to the risk factor section of our September 30, 10-Q for more information on those risks." McL. Decl. Ex. EE at 3.

[45] Notably, several statements identified in the Complaint were made *before* the plaintiffs contend that Genzyme made an "internal decision" not to market Lumizyme. The plaintiffs cite a December 15, 2009 reference by Mr. Termeer to the company's decision regarding Lumizyme on an unspecified date in March 2009. *See* Compl. ¶ 126.

As an initial matter, the allegation fails on its face to establish loss causation — also an element of a Section 10(b) claim, *see Dura*, 544 U.S. at 342 — because the allegedly "corrective" disclosure was made well after the end of the putative class period. A motion to dismiss must be granted where — as here — the plaintiff fails adequately to allege that a material misstatement or omission was the cause of the actual loss suffered. *See In re Polaroid Corp. Sec. Litig.*, 134 F. Supp. 2d 176, 188 (D. Mass. 2001) (internal quotations omitted) (granting motion to dismiss for failure to establish loss causation because "[a] plaintiff must allege that the misstatements were the reason the transaction turned out to be a losing one"). To establish loss causation:

> a plaintiff must allege . . . that the subject of the fraudulent statement or omission was the cause of the actual loss suffered, *i.e.*, that the misstatement or omission concealed something from the market that, when disclosed, negatively affected the value of the security. Otherwise, the loss is not foreseeable.

In re Alkermes Sec. Litig., No. 03-CV-12091, 2005 WL 2848341, at *11 (D. Mass. Oct. 6, 2005) (*quoting Lentell v. Merrill Lynch & Co., Inc.*, 396 F.3d 161 (2d Cir. 2005)) (quotations omitted).

There can be no dispute that the plaintiffs have failed to plead *any* causal link between the information allegedly withheld — that is, Genzyme's decision regarding which specific production scale would be used to meet demand in a particular market — and the loss the plaintiffs allegedly suffered — a drop in the Company's stock price. *See* Compl. ¶¶ 321, 322. Indeed, the Complaint fails to even include the decision not to market Lumizyme produced at the 2000L scale in its loss causation allegations. *Id.* This is hardly surprising, since it is not possible that any relevant drop in the market price of Genzyme's stock during the putative class period was attributable to the purportedly "corrective" disclosure of the decision regarding Lumizyme.

Thus, even if it is assumed true that Genzyme made that decision at some point in March 2009, the plaintiffs' failure to specify a date in March forecloses any viable claim of a misstatement or omission made prior to the end of that month. *See* Compl. ¶¶ 280, 283.

The plaintiffs themselves claim that the corrective disclosure was made on December 15, 2009 — a full month after the end of the putative class period. Compl. ¶ 126. Loss causation cannot be present where no corrective disclosure of the purportedly "true" facts can possibly have been the cause of a stock price decline and any resulting injury to the plaintiffs during a relevant time. Because the Complaint fails in this way to allege an essential element of a securities fraud claim, the alleged "omission" cannot survive a motion to dismiss.

Moreover, while the Complaint seeks to make much of Genzyme's failure to disclose the March 2009 decision to meet United States demand with the larger scale 4000L product rather than continue to pursue the sale of 2000L Lumizyme, the plaintiffs cannot allege — and have not alleged beyond conclusory 'say so' — that the information even was material. The Complaint was required to "articulate facts that show how the omitted information would have significantly altered the total mix of information available to the market." *Praecis*, 2007 WL 951695 at *18.

Nowhere do the plaintiffs even attempt to explain how disclosure in March 2009 would have altered the "total mix" of information available to the market. Genzyme announced well before March 2009 that it intended to pursue approval of 4000L Lumizyme in the United States — thus the plaintiffs cannot suggest that the Company's growing emphasis on the larger scale version of Lumizyme was somehow hidden. *See* McL. Decl. Ex. CC at 13, 17 (Tr. of Earnings Conf. Call, Oct. 22, 2008) (discussing seeking 4000L approval in U.S.); Ex. J at 2 (Press Release and Form 8-K, Jan. 13, 2009) ("The company anticipates filing for U.S. approval for the 4000L manufacturing process during the first half of this year."). In fact, the very disclosures the Complaint characterize as fraudulent in this regard specified the Company's plans to submit an sBLA for 4000L Lumizyme that would replace the smaller scale 2000L Lumizyme production. *See* McL. Decl. Ex. FF at 4, 10, 11 (Tr. of Investor Conf. Call, Mar. 2, 2009); Ex. V at 9 (Form

10-K for 2008, Mar. 2, 2009); Ex. TT (Press Release and Form 8-K, Apr. 22, 2009); Ex. OO at 18 (Press Release and Form 8-K, Oct. 21, 2009). In short, the Company realized that its ability to sell Lumizyme produced at the 4000L scale rendered unnecessary the marketing of 2000L Lumizyme in the U.S. It is telling that the Complaint does not suggest that the larger scale product would be unable to "fill Lumizyme's shoes" for the United States market — rather, the plaintiffs simply quibble with the Company's disclosures without addressing in any specific manner how the disclosures were *materially* misleading at all. In view of the extensive disclosures made by the defendant regarding its intention to pursue 4000L approval and the lack of any allegation that the "internal decision" would result in a shortfall of product in any market, the plaintiffs cannot possibly claim that any alleged omissions regarding Lumizyme plans would alter the total mix of information available. For this additional reason, their claim based on this statement should be dismissed.

CONCLUSION

For the foregoing reasons, the defendants respectfully request that the Court dismiss the plaintiffs' Complaint in its entirety, with prejudice.

Dated: June 2, 2010 Respectfully submitted,

/s/ John D. Donovan, Jr.
John D. Donovan, Jr. (BBO# 130950)
Robert G. Jones (BBO# 630767)
Alison E.H. McLaughlin (BBO# 663060)
ROPES & GRAY LLP
One International Place
Boston, Massachusetts 02110
(617) 951-7000 (Tel)
(617) 951-7050 (Fax)

Counsel for Defendant Genzyme Corporation